electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 4.0 (2023-06-12)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? **Blue Help Text Buttons** when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: For technical issues or bug reports please email eSubPilot@fda.hhs.gov.
For regulatory process or content questions please email:
USFDA: DICE@fda.hhs.gov
Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type, attachment name, or size restriction?
A: Unacceptable attachment types and names are automatically prevented. If an attachment is great than 1 GB,

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g. 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g. 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

Application/Submission Type

Application Jurisdiction	(•) US FDA ( ) Health Canada

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(•) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	(•) New Application/Submission ( ) Additional Information

Cover Letter / Letters of Reference

Add Attachment | Attach your Cover Letter | ?

Open Attachment | DOC-0024_Cover_Letter.docx.pdf | Delete Attachment

Add Attachment | Attach any Letters of Reference | ?

Applicant Information ?

Contact

Title: Dr. | Last Name: Shrestha | First Name: Yujan

Email: fda@innolitics.com | Phone Number: (512) 967-6088

Occupation Title: CTO and Co-Founder

Company

Company Name: Innolitics, LLC

Address - Line 1: 1101 West 34th St

Address - Line 2: #550

City: Austin | State: TX | Zip: 78705 | Country/Region: United States

Add Correspondent/Consultant

Primary Correspondent/Consultant Information

Contact

Title: | Last Name: Martinez | First Name: Meritxell

Email: mmartinez@innolitics.com | Phone Number: 956-543-8140

Occupation Title: Project Manager and Regulatory Specialist

Company

Company Name: Innolitics, LLC

Address - Line 1: 1101 West 34th St

Address - Line 2: #550

City: Austin | State: TX | Zip: 78705 | Country/Region: United States

Add Correspondent/Consultant | Delete Correspondent/Consultant

Correspondent/Consultant Information

Contact

Title		Last Name	Ulrich	First Name	Ethan
Email	eulrich@innolitics.com			Phone Number	
Occupation Title	Software Engineer				

Company

Company Name	Innolitics, LLC				
Address - Line 1	1101 West 34th St				
Address - Line 2					
City	Austin	State	TX	Zip	78705
Country/Region	United States				

Add Correspondent/Consultant | Delete Correspondent/Consultant

Correspondent/Consultant Information

Contact

Title		Last Name	Luker	First Name	Jim
Email	jluker@innolitics.com			Phone Number	
Occupation Title	VP of Regulatory Affairs				

Company

Company Name	Innolitics, LLC				
Address - Line 1	1101 West 34th St				
Address - Line 2					
City	Austin	State	TX	Zip	78705
Country/Region	United States				

Add Correspondent/Consultant | Delete Correspondent/Consultant

Correspondent/Consultant Information

Contact

Title	Dr.	Last Name	Shrestha	First Name	Yujan
Email	yshrestha@innolitics.com			Phone Number	
Occupation Title	CTO and Co-Founder				

Company

Company Name	Innolitics, LLC
Address - Line 1	1101 West 34th St
Address - Line 2	
City	Austin
State	TX
Zip	78705
Country/Region	United States

Add Correspondent/Consultant | Delete Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? Yes ?

Add Submission

Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

Q222933 | Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information requests.

Open Attachment	Q222933.FDA Written Feedback.pdf	Delete Attachment
Open Attachment	Q222933.MeetingMinutes.REVS.pdf	Delete Attachment
Open Attachment	DOC-0050_Q222933_Presub_Response_to_FDA_Feedback.pdf	Delete Attachment

Standards ?

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. A recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators request standards information be attached, see help text.

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

CT Cardiomegaly	v.1.0.0	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	No
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	Yes

• Please check the attributes that are applicable to your device.

- ☐ Cloud Communication
- ☐ Network connection (active or not)
- ☐ Wireless communication in any form
- ☐ USB/serial ports/removable media
- ☐ Software upgrades (this includes patches)
- ☒ None of the above

Is the device or a component packaged as sterile?	No

The device/system uses or is... (choose all that apply)

- ☐ a single use device(s), non-sterile or packaged as sterile
- ☐ a single use device(s), terminal/end user sterilized
- ☐ a reusable single patient use device(s)
- ☒ a reusable multi-patient use device(s)

The environment of use of the device/system includes... (choose all that apply)

- ☒ Professional Healthcare Facility
- ☐ Home Environment
- ☐ Magnetic Resonance (MR) Environment
- ☐ Transport (Ambulatory) Environment
- ☐ Other Environment

Is the device a combination product or does a Request For Designation (RFD) / pre-RFD exist for the product?	No (most common)
Is the device electrical (battery or wall powered)?	No, the device is not electrical

Please check the attributes that are applicable to your device. If none apply, keep all unchecked.

- ☐ Medical Counter Measures Device
- ☐ Nanotechnology
- ☐ Reprocessed Single Use Device
- ☐ Animal-Derived Material(s)
- ☐ Predetermined Change Control Plan

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The CT Cardiomegaly application is a software only (SaMD) medical device which includes automated algorithms and non-adaptive machine learning to analyze previously obtained chest computed tomography (CT) images. CT Cardiomegaly is a command line software intended to be run on its own or as part of another medical device.

CT Cardiomegaly scans the existing images for the presence of specific anatomical structures (i.e., heart and chest cavity). If the target structures are present, the software segments and performs automated measurements which may be helpful in assisting with the detection of certain diseases and/or conditions (i.e., cardiomegaly). The quantitative information is provided to the clinician in the form of a summary report. The clinician (using all available information) then decides if further diagnostic work-up is indicated. The results from CT Cardiomegaly are not intended to be used as the primary input for clinical-decision making or diagnosis but rather are intended to provide information which may assist the clinician to identify anatomical 'findings of interest' within existing imaging studies.

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	DOC-0031_Device_Description.pdf	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	DOC-0032_Device_Schematic.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?

System/Kit Components and Accessories

Is the device intended to be marketed with multiple system/kit components or accessories? No ?

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

CT Cardiomegaly has a quantitative imaging function as defined in FDA's 2022 Guidance "Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions".
A description of the quantitative imaging function as recommended by FDA's guidance can be found in DOC-0040 Software Description.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

CT Cardiomegaly (v.1.0.0)

Indications for Use *(Describe)*

CT Cardiomegaly is a command line software application intended to be run on its own or as part of another medical device to automatically calculate linear and area based cardiothoracic ratio (CTR) from a CT image containing the heart.

CT Cardiomegaly is designed to measure the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity and calculate the CTR from an axial CT slice containing the heart using a non-adaptive machine learning algorithm.

Intended users of the software are aimed to the physicians or other licensed practitioners in the healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services.

The system is suitable for adults between 20 - 80 years of age.

Its results are not intended to be used on a stand-alone basis for clinical-decision making or otherwise preclude clinical assessment of any disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450). ?

Medical Specialty	Radiology
Regulation	892.2050 - Medical image management and processing system
Product Code	QIH (Class 2) - Automated Radiological Image Processing Software
Associated Product Code(s)	?

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	No
Predicate Submission Number (e.g., K210001)	K212624
Predicate Device Trade Name	EFAI Intelligent Cardiothoracic Ratio (iCTR) Assessment Syst
Predicate Device Primary Product Code	

Medical Specialty	Radiology
Regulation	892.2050 - Medical image management and processing system
Product Code	QIH (Class 2) - Automated Radiological Image Processing Software

Add Predicate/Reference Device | Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Both the subject (CT Cardiomegaly) and predicate device (EFAI Intelligent Cardiothoracic Ratio (iCTR) Assessment System) have identical indications for use, with the exception that the subject device analyzes CT images while the predicate device is limited to X-ray images.

Another difference between the indications for use for both devices is that the predicate uses an artificial intelligence algorithm while the subject device utilizes a non-adaptive machine learning algorithm using the MONAI framework.

However, these differences in technological characteristics do not affect safety and effectiveness of the device, and have been supported with appropriate verification and validation testing.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

?

The CT Cardiomegaly has similar technological characteristics as compared to the predicate device. Both devices are intended to be used by physicians or other licensed practitioners in healthcare institutions. Additionally, both devices are intended to be used in patients aged 20-80. Both devices use software algorithms to analyze post-anterior (PA) view of medical images of the chest and provide automated diameter measurements.

CT Cardiomegaly also has some differences in technological characteristics when compared to its predicate device. The main differences are listed below:

- Imaging modality: The subject device analyzes CT images while the predicate device analyzes X-Ray images. However, this difference in imaging modality does not raise any new questions of safety or effectiveness, and has been supported with verification and validation testing.

- CTR measurement: The subject device's output measurements include both linear-based CTR and area-based CTR. The predicate device only includes linear-based CTR. Although the output measurement of area-based CTR is not supported by the predicate device, it does not raise different questions of safety or effectiveness and has been supported with verification and validation testing.

- Output format: The output format of the predicate device includes reports and DICOM secondary capture series, while the subject device's only output format is a report (in both PDF and JSON format). Thus, the subject device's output format is a subset of the predicate's available output formats (i.e., report). This lack of a feature does not raise any new questions of safety or effectiveness.

- Reference value(s): The subject device introduces a feature to have reference value(s). The healthcare professional is able to adjust reference value(s), for both linear and area-based CTR, based on published literature or their practice of medicine. This feature does not affect the raw CTR measurement, but is rather intended for the user to be able to flag values above certain thresholds as desired by the user. Although this feature is not supported by the predicate device, it does not raise different questions of safety or effectiveness and has been supported with verification and validation testing.

Add Attachment

Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s).
If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.

?

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	DOC-0013 User Manual, p. 18	?
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	Not Evaluated	?
If the device(s) contains a static/permanent magnet, please specifically cite the attachment and page number where labeling includes a statement and/or contraindication regarding the risk of magnet use within 6 inches of other magnetically susceptible medical devices. Type "N/A" if not applicable.	N/A - Device is SaMD	?

Package Labeling

Add Attachment — Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging. ?

Open Attachment — Package_Labeling_Justification.pdf — Delete Attachment

Package Insert / Instructions for Use

Add Attachment — Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website. ?

Open Attachment — DOC-0013_User_Manual.pdf — Delete Attachment

Other Labeling

Add Attachment — Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option. ?

e-Labeling

Open Attachment — DOC-0027_Software_Label.pdf — Delete Attachment

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	The prescription statement is found in both the Software Label	?
Please specifically cite the attachment and page number where	DOC-0013 User Manual, p. 5	

Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	The name and place of business of the manufacturer is found in both the Software Label (DOC-0027, p.

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

CT Cardiomegaly has quantitative imaging functions as defined in FDA's Guidance "Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions". The recommended labeling information has been included in DOC-0013 User Manual, p. 8, 13, and 17.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Reprocessing, Sterility, and Shelf-Life

Based on the answers provided in the Device Description section, reprocessing information, but no sterility information, is needed.

Reprocessing

?

Are cleaning or disinfection or sterilization instructions included in the labeling? No

Please provide a rationale for why cleaning/disinfection instructions are not included in the labeling.

Subject device is SaMD.

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A - Subject device is SaMD

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life? No ?

Please summarize the methods used to support that the sterility and performance of the device is not adversely affected by aging. Alternatively, include a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

N/A - Subject device is SaMD

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment

Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment. ?

Biocompatibility

Based on the answer provided in the Device Description section, no biocompatibility information is needed.

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, only software information is needed.

Software / Firmware / Programmed or Programmable Medical Device ?

Software Documentation Level

Please select the Documentation Level based on the device's intended use, the design of the device, and the risks of the device software function(s) in the context of the device's intended use.

Enhanced Documentation: This should be chosen for any premarket submission that includes device software function(s), where a failure or flaw of any device software function(s) could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use. These risks should be assessed prior to implementation of risk control measures. Sponsors should consider the risks in the context of the device's intended use (e.g., impacts to safety, treatment, and/or diagnosis), and other relevant considerations.

Basic Documentation: This should be chosen for any premarket submission that includes device software function(s) where Enhanced Documentation does not apply.

Basic Documentation

Add Attachment	Documentation Level Evaluation ?	
Open Attachment	DOC-0033_Documentation_Level_Evaluation.pdf	Delete Attachment

The software documentation below is recommended for the documentation level specified. Click on the blue help text buttons for details about what is recommended in the documentation for each.

Software Documentation

Add Attachment	Software / Firmware Description ?	
Open Attachment	DOC-0040_Software_Description.pdf	Delete Attachment
Open Attachment	DOC-0047_SOUP_OTS_Report.pdf	Delete Attachment
Open Attachment	DOC-0039 Software Bill of Materials.pdf	Delete Attachment
Open Attachment	DOC-0039 Software Bill of Materials (Machine Readable).xml	Delete Attachment
Add Attachment	Risk Management File (including Hazard Analysis) ?	
Open Attachment	DOC-0004_Risk_Management_Plan.pdf	Delete Attachment
Open Attachment	DOC-0007_Risk_Assessment.pdf	Delete Attachment
Open Attachment	DOC-0019_Risk_Management_Report.pdf	Delete Attachment
Add Attachment	Software Requirements Specifications (SRS) ?	
Open Attachment	DOC-0006_Software_Requirements_Specification.pdf	Delete Attachment
Add Attachment	System and Software Architecture Design Chart ?	
Open Attachment	DOC-0008_System_and_Software_Architecture_Diagram.pdf	Delete Attachment

Add Attachment	Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices		?
Open Attachment	DOC-0003_Product_Development_Plan (Software Development	Delete Attachment	
Add Attachment	Software Testing as Part of Verification & Validation		?
Open Attachment	DOC-0044_Software_Verification_Plan.pdf	Delete Attachment	
Open Attachment	DOC-0045_Software_Verification_Report.pdf	Delete Attachment	
Open Attachment	DOC-0048_Traceability_Analysis.pdf	Delete Attachment	
Add Attachment	Software Revision Level / Version History		?
Open Attachment	DOC-0046_Software_Version_History.pdf	Delete Attachment	
Add Attachment	Unresolved Software Anomalies		?
Open Attachment	DOC-0049_Unresolved_Software_Anomalies.pdf	Delete Attachment	

EMC, Wireless, Electrical, Mechanical, and Thermal Safety ?

Based on the answers provided in the Device Description section, no EMC or wireless technology information is needed. You should still address Mechanical and Thermal safety testing in the textbox below.

Electrical, Mechanical, and Thermal Safety Summary

Please summarize the Electrical, Mechanical and Thermal Safety Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence). ?

N/A - subject device is SaMD.

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

Performance Testing

Was Bench Testing used in order to support this submission?	No
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	Yes

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here. ?

Nonclinical testing of the CT Cardiomegaly device included software verification and validation testing.

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.) ?

A Clinical Performance Assessment was conducted to compare the measurements reported by CT Cardiomegaly against manual measurements of intended users (see DOC-0052 and DOC-0053). This clinical testing is not a formal clinical study or trial.

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above. ?

Clinical Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.	K212624

Add Attachment	Please attach documentation that includes details of the clinical testing performed with your device. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission. Choose the attachment type in the dropdown for each attachment.	?

Clinical Evalution Report

Open Attachment | DOC-0053_Clinical_Performance_Assessment_Report.pdf | Delete Attachment

Other Clinical Evidence

Open Attachment | DOC-0052_Clinical_Performance_Assessment_Protocol.pdf | Delete Attachment

Other Clinical Evidence

Open Attachment | Allen CV.pdf | Delete Attachment

Other Clinical Evidence

Open Attachment | Rothenberg CV.pdf | Delete Attachment

Other Clinical Evidence

Open Attachment | Smith CV.pdf | Delete Attachment

Patient-Reported Outcomes and Patient Preference Information

Does your clinical testing include patient-reported outcomes (PROs) or patient preference information (PPI)?	No	?

Compliance with Good Clinical Practice for Supporting Clinical Investigations

Is one or more of the included clinical investigations intended to support this submission subject to the requirements governing FDA acceptance of data from clinical investigations? Click the Help Text button for more information.	No	?

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

The subject device is a SaMD and thus followed FDA's 2023 guidance for "Content of Premarket Submissions for Device Software Functions" in drafting system-level protocols and reports, and providing summary of activities of unit and integration testing. This information can be found in DOC-044 Software Verification Plan and DOC-0045 Software Verification Report.

Additionally, a clinical performance assessment was conducted as detailed in DOC-0052 and DOC-0053

This testing, in part, followed the guidance outlined in FDA's 2022 guidance for Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

References

Is literature referenced in the submission?	No	?

Administrative Documentation

Add Attachment	General Summary of Submission/Executive Summary	?
Add Attachment	Financial Certification and Disclosure Statement (Form FDA-3454 and/or 3455)	?
Open Attachment	Clinical_Performance_Justification__Forms_3454_and_3455.pdf	Delete Attachment
Add Attachment	Clinical Trials Certification Form (Form FDA-3674)	?
Open Attachment	Clinical_Performance_Justification__Form_3674.pdf	Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(l)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.	No

Add Attachment	Please use the link above to download the Truthful and Accurate statement. Please have a responsible party of the 510(k) owner print and sign this document, then scan and upload this document here.	
Open Attachment	DOC-0054_Truthful_and_Accurate_Statement.pdf	Delete Attachment

Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	Yes

Add Attachment	510(k) Summary or Statement	
Open Attachment	DOC-0025_510k_Summary.pdf	Delete Attachment
Add Attachment	Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.	?
Open Attachment	Innolitics_ MDUFMA Cover Sheet.pdf	Delete Attachment

Please enter in the User Fee Payment Identification Number.	MD6139632	?

Show User Fee Introduction

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Performance Testing
References
Administrative Documentation

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Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.
Admin Functions	FOR ADMINISTRATOR USE ONLY

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

Please submit this eSTAR PDF for review using the CDRH Portal unless your medical device is regulated by the Center for Biologics Evaluation and Research (CBER) or is a combination product where CBER is the lead. You do not need to send any documentation in physical form using mail couriers.

For CBER-regulated medical devices or for combination products where CBER is the lead, please refer to Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products for information on how to submit to CBER through the Electronic Submission Gateway.