inHEART, SAS
℅ Audrey Labèque
Quality and Regulatory Affairs Manager
IHU LIryc – Hôpital Xavier Arnozan-Avenue du Haut Lévêque
Pessac, 33600
FRANCE

May 10, 2022

Re: K220727
Trade/Device Name: inHEART MODELS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 11, 2022
Received: March 14, 2022

Dear Audrey Labèque:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Division Director
DHT8B: Imaging Devices and
Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.

510(k) Number *(if known)*
K220727

Device Name

inHEART MODELS

Indications for Use *(Describe)*

inHEART MODELS comprises a suite of medical imaging software modules that are intended to provide qualified medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. inHEART MODELS accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT and MR. The software is designed to be used by qualified medical professionals (including physicians, cardiologists, radiologists, and technicians) and the users are solely responsible for making all final patient management decisions.

CONTRAINDICATIONS:
This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

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.

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Chapter 6. 510(k) Summary

Submitter's Name:	inHEART, SAS
Address:	IHU Liryc – Hôpital Xavier Arnozan Avenue du Haut Lévêque 33600 Pessac, France
Contact: Telephone: Date:	Audrey Labèque, Quality and Regulatory Affairs Manager +33 5 35 38 19 72 March 11, 2022
Trade Name:	inHEART MODELS
Common Name:	Picture Archiving and Communications System (PACS)
Classification Name(s):	Medical Image Management and Processing System (21 CFR 892.2050)
Classification Number(s):	LLZ
Regulatory Class:	Class II
Predicate Device:	K200973 – Synapse 3D Cardiac Tools, FUJIFILM Healthcare Americas Corporation

1. Device Description

inHEART MODELS is a suite of medical image processing software tools that enables 3D visualization and analysis of anatomical structures. Specifically, the software modules read DICOM compatible anonymized pre-operative CT and MR images acquired by commercially available imaging devices. These images are then processed to generate 3D models of the anatomy to allow qualified medical professionals to display, review, analyze, annotate, interpret, export, and plan therapeutic interventions. inHEART MODELS includes two non-device Medical Device Data Systems (MDDS) modules that are only intended to transfer, store and convert formats.

inHEART MODELS complies with the following standards:

- ISO, 14971 Third Edition 2019-12, Medical devices – Application of Risk Management to medical devices
- ISO, 15223-1 Third Edition 2016-11-01, Medical devices – Symbols to be used with medical device labels, labeling and information....
- IEC, 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION: Medical device software – Software life cycle processes
- IEC, 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION: Medical devices – Part 1 : application of usability engineering to....
- IEC, /TR 80002-1 Edition 1.0 2009-09, Medical device software – Part 1 : Guidance of the application of ISO 14971 to medical device..
- IEC, 82304-1 Edition 1.0 2016-10, Health software – Part 1 : General requirements for product safety

2. Indications for Use

inHEART MODELS comprises a suite of medical imaging software modules that are intended to provide qualified medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. inHEART MODELS accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT and MR. The software is designed to be used by qualified medical professionals (including physicians, cardiologists, radiologists, and technicians) and the users are solely responsible for making all final patient management decisions.

CONTRAINDICATIONS:

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

3. Comparison of technological characteristics with the predicate device

The inHEART MODELS software is substantially equivalent to the predicate that has already been cleared for USA distribution with 510(k) premarket notification number K200973. Briefly, the subject and predicate devices are based on the following same technological elements:

- Software tools for the visualization of DICOM compliant CT and MR images
- Permit specialized measurement of anatomic structures
- Support for multiple operating systems and computer hardware configurations
- Various image processing, meshing and image registration tools supported
- Support for 2D and 3D visualization tools
- Export of images and reports in various formats

The following technological differences exist between the subject and predicate device:

- The subject device is a standalone and web-based software suite whereas the predicate device is standalone and server/client configuration installed on a commercial general-purpose Windows-compatible computer
- Vessel segmentation is not available in the predicate device
- A software feature to automatically extract the heart and coronary arteries from CT and MR images available on the predicate device is not available on the subject device
- Some image processing tools used in the subject device were not available in the predicate device (Gaussian filter, frame extraction, merge volumes, meshing tools, navigation through slices, display/hide structures, colors, 3D rendering modes, export formats)

4. Performance data

The following performance data were provided in support of the substantial equivalence determination :

Software verification and validation testing were conducted on all inHEART MODELS software modules and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*"
inHEART MODELS was considered as a "moderate" level of concern.

In addition, accuracy of segmentations for inHEART MODELS was compared to ground truth and to previously cleared commercially available comparable software tools. CT and MR images were selected for the performance study. In-house analysts generated 3D

heart models from the imaging data. Radiologists were designated as ground-truth annotators. All validation criteria were met, and the performance evaluation study demonstrated that output segmentations and measurements on these segmentations for inHEART MODELS were substantially equivalent to previously cleared legally marketed software devices.

No new safety or efficacy issues were introduced by inHEART MODELS compared to the predicate device. There are no differences in indications for use between the inHEART MODELS and the predicate Synapse 3D Cardiac Tools (K200973).

Furthermore, performance data demonstrate that the functionality, output and clinical usage of inHEART MODELS is substantially equivalent to the predicate device.