AI Medic Inc.
℅ Jeong Song
COO
2F, 437, Bongeunsa-ro, Gangnam-gu
Seoul, KS013/06097
REPUBLIC OF KOREA

July 20, 2022

Re: K220039
Trade/Device Name: AutoSeg-H
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 21, 2022
Received: June 28, 2022

Dear Jeong Song:

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,

Jessica Lamb, Ph.D.
Assistant Director
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K220039

Device Name
AutoSeg-H

Indications for Use *(Describe)*
AutoSeg-H is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. AutoSeg-H accepts DICOM compliant medical images acquired from imaging device (Computed Tomography).

AutoSeg-H provides the tools for specific analysis applications which provide custom UI, targeted measurements and reporting functions including:
- Coronary Artery Analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries.
- Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves.
- 4-Chamber Analysis: which is intended for automatic extraction of the left atrium, left ventricle, right atrium, and right ventricle from CT.

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.

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Tel: +82-(0)2-568-2667 Fax:+82-(0)2-548-2667

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

July 11, 2022

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: AI Medic Inc.
- Address: 2F, 437, Bongeunsa-ro, Gangnam-gu, Seoul, 06097, Republic of Korea
- Contact Name: Jeong Soon Song/COO
- Telephone No.: +82-2-568-2667
- Fax No.: +82-2-548-2667
- Email Address: song@aimedic.kr

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Picture archiving and communications system (PACS)
Trade name: AutoSeg-H (Model: AutoSeg-H)

Classification Description	21 CFR Section	Product Code
System, Image Processing, Radiological	21 CFR 892.2050	LLZ

As stated in 21 CFR parts 892.2050 of the device has been classified as Class II.

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device

- 510(k) Number: K200973
- Applicant: FUJIFILM Corporation
- Classification Name: System, Image Processing, Radiological
- Trade Name: Synapse 3D Cardiac Tools
- Common Name: Picture archiving and communications system (PACS)

5. Description of the Device [21 CFR 807.92(a)(4)]

5.1 Overview

AutoSeg-H(V1.0.0.01) is software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. AutoSeg-H(V1.0.0.01) runs on Windows standalone installed on a commercial general-purpose Windows-compatible computer and accepts DICOM compliant medical images acquired from a CT. The AutoSeg-H is not connected to a PACS system directly but retrieves saved image data from a computer. Image data obtained from the computer are used for display, image processing, analysis, etc. AutoSeg-H cannot be used to interpret Mammography images.

The main functions of AutoSeg-H are shown below.

- Coronary Artery Analysis (CT)
- Aortic Valve Analysis (CT)
- 4-Chamber Analysis (CT)

- AutoSeg-H Block Diagram

The connection configurations for AutoSeg-H are shown below.

• AutoSeg-H operates on a window.
• AutoSeg-H reads the CT DICOM image from its own device and analyzes them. (Standalone configuration)

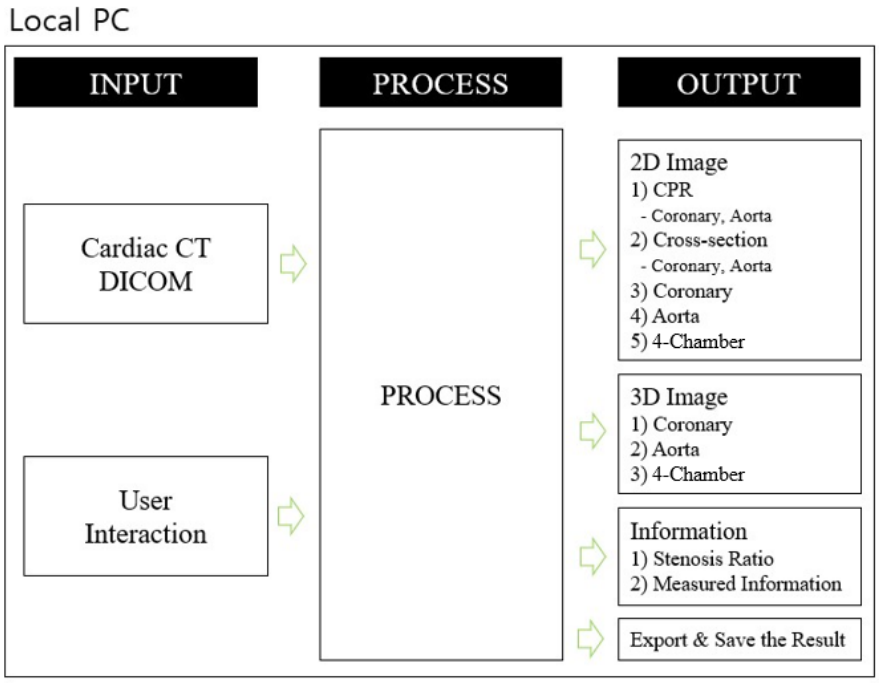

Fig. Block Diagram

- AutoSeg-H algorithm description

The software employs an advanced active contour algorithm with entropy regularization, to implement semantic segmentation of target organs. The execution of this method results in 3D reconstruction of target organs.

5.2 AutoSeg-H Applications

In the configurations shown in Block diagram(Fig) offers trained medical professionals the following applications to analyze the image data retrieved from Computed tomography.

- General Applications

1. Menu

In the Menu application, user can import DICOM, load previous work file, extract 3D model, and save work files.

2. 2D Viewer

The 2D Viewer can show axial view, sagittal view, coronal views of coronary artery, aorta, and 4-chamber.

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3. 3D Viewer (3D reconstruction)

The 3D Viewer can show 3D reconstructed coronary artery, aorta, and 4-chamber.

4. Measurement

The Measurement application can show what the user measured like distance between two points, angle, area, and perimeter of 2D and 3D view etc.

5. Manual Image Modification (Editing)

By the modification application, users can select, draw, modify, and label specific areas on 2D or 3D view etc. .

6. Sequential Display

The Sequential Display, sequentially displays a cross section of specified area. (Angle, play range, speed, direction can be set)

7. Setting

In the Setting application, users can set brightness, initialize histogram, sync images, set 3D reconstruction image as volume, solid mesh and wire frame view, turn on/off patient information, coordinate display, crosshair and 3D view.

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- Analysis Applications

1. Coronary Artery Analysis

   The Coronary Artery Analysis application can reconstruct 3D Coronary Artery, display CPR view, display Cross section view, analyze Stenosis ratio, initialize the layout and turn on/off the Coronary Artery, Coronary Inner line.

2. Aortic Valve Analysis

   The Aortic Valve Analysis application can reconstruct 3D Aorta, mark the centerline, measure long axis, short axis, area, perimeter, and rotate the 3D image. Also can switch to the default layout, manually select the measurement location, initialize/save/display the measurement result.

3. 4-Chamber Analysis

   The 4-Chamber Analysis application can reconstruct 3D left atrium, left ventricle, right atrium, and right ventricle.

5.3 Technical Characteristics and principles of operations

Predicate Device: A software program used for medical image analysis, of which segmentation method is based on a graphical model for pattern recognition.

Subject Device: A software program used for medical image analysis, of which segmentation method is based on an advanced active contour algorithm for pattern recognition.

Different equations of safety and effectiveness? No

Why: Since both devices receive input data as DICOM compliant CT images and handle it with numerical algorithms, there is no specific reason for raising new or different questions of safety and effectiveness although the new device features different technical characteristics and principles of operations.

2F, 437, Bongeunsa-ro, Gangnam-gu, Seoul, 06097, Republic of Korea
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6. Indications for Use [21 CFR 807.92(a)(5)]

AutoSeg-H is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. AutoSeg-H accepts DICOM compliant medical images acquired from imaging device (Computed Tomography).

AutoSeg-H provides the tools for specific analysis applications which provide custom UI, targeted measurements and reporting functions including:

- Coronary Artery Analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries.

- Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves.

- 4-Chamber Analysis: which is intended for automatic extraction of the left atrium, left ventricle, right atrium, and right ventricle from CT.

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7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

The identified predicate device within this submission are shown in the following table:

	Proposed Device	Predicate Device	SE decision
K Number	K220039	K200973	-
Manufacturer	AI Medic Inc.	FUJIFILM Corporation.	-
Trade name	AutoSeg-H	Synapse 3D Cardiac Tools	
Model	AutoSeg-H	V5.4	-
Product Code	LLZ	LLZ	Same
Regulatory Class	Class II	Class II	Same
Regulation Number	21 CFR 892.2050		Same
Indications for Use	AutoSeg-H is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. AutoSeg-H accepts DICOM compliant medical images acquired from imaging device (Computed Tomography). AutoSeg-H provides the tools for specific analysis applications which provide custom UI, targeted measurements and reporting functions including: - Coronary Artery Analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries. - Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves. - 4-Chamber Analysis: which is intended for automatic extraction of the left atrium, left ventricle, right atrium, and right ventricle from CT.	Synapse 3D Cardiac Tools is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals with tools to aid them in reading interpreting, reporting, and treatment planning, Synapse 3D Cardiac Tools accepts DICOM compliant medical images acquired from a variety of imaging devices including, CT, MR, NM, and XA. This product is not intended for use with or for the primary diagnostic interpretation of Mammography images. Addition to the tools in Synapse 3D Base Tools, Synapse 3D Cardiac Tools provides the tools for specific clinical applications which provide targeted workflows, custom UI, targeted measurements and reporting functions including: □ Functional cardiac analysis for CT left ventriculography images: which is intended to evaluate the functional characteristics of heart. □ Functional cardiac analysis for MR heart images: which is intended to evaluate the functional characteristics of heart. □ Coronary artery analysis for CT coronary arteriography images: which is	Same

		intended for the qualitative and quantitative analysis of coronary arteries. □ Coronary artery analysis for MR heart images: which is intended for the qualitative and quantitative analysis of coronary arteries. □ Calcium scoring for non-contrast CT heart images: which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms. □ Cardiac Fusion: which is intended to analyze cardiac anatomy and pathology with a fused image of functional data (e.g. NM image, Bulls eye) and anatomical data. □ Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves, measurement of the calcification area in the aorta and the valves. Placement of a virtual prosthetic valve. □ MR parametric maps: which is provided for pixel maps for myocardial MR relaxation times.	
Users	Healthcare Professionals	Healthcare Professionals	Same
DICOM compliant medical images	CT	CT, MR, NM and XA	
Imaging Capabilities	2D, 3D	2D, 3D	Same
Function	Coronary Artery Analysis (CT), Aortic Valve Analysis (CT), 4-Chamber Analysis (CT)	Cardiac Function(CT,MR), Coronary Artery Analysis(CT,MR), Calcium Scoring, Cardiac Fusion, Aortic Valve Analysis, MR Flow Analysis(MR), 4-Chamber Analysis(CT), Cardiac Ablation Analysis(CT), Cardiac Tx-maps, Mitral Valve Analysis	
Product Availability	Software Product	Software Product	Same
Hardware Platform	Windows PC	Windows PC	Same
Operating System	Windows 10(x64)	Microsoft Windows 10 (x64, x86) Microsoft Windows 8.1 (x86, x64)	

		Microsoft Windows 7 Professional (x86, x64) SP1	
Performance Standards	Digital Imaging and Communications in Medicine (DICOM) Set (Ps3.1 - .20) AAMI/ANSI/IEC 62304:2006, Medical Device Software ISO 14971 Second Edition 2007-03-01, Medical Devices	Digital Imaging and Communications in Medicine (DICOM) Set (Ps3.1 - .20) AAMI/ANSI/IEC 62304:2006, Medical Device Software ISO 14971 Second Edition 2007-03-01, Medical Devices	Same
Core Technology and Algorithm	**Segmentation Method Based on Advanced Active Contour Algorithm** The software employs an advanced active contour algorithm with entropy regularization, to implement semantic segmentation of target organs. The execution of this method results in 3D reconstruction of target organs.	The segmentation algorithm is a kind of graphical model solving energy minimization problem in terms of image energies, providing 3D reconstruction of target organs.	Same

Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

Non-clinical performance testing has been performed in compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 14971 Second Edition 2007-03-01, Medical Devices – Application of Risk Management to Medical Devices
- AAMI/ANSI/IEC 62304:2006, Medical Device Software – Software Life Cycle Processes
- Digital Imaging and Communications in Medicine (DICOM) Set (PS 3.1 – 3.20) (2016)
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Performance tests were conducted for the following purposes:

- To confirm that AutoSeg-H meets all performance test criteria and all functions are operating without errors.
- To confirm that AutoSeg-H meets test standards which estimation of the quantitative measurement error.
- To confirm that AutoSeg-H meets test standards which estimation of segmentation algorithm error.

Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to formalize after ensuring that the software fully satisfies all expected and previously defined system requirements and features.

Through the performance test, it was confirmed that AutoSeg-H meets all performance test criteria and that all functions work without errors. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate device.

2F, 437, Bongeunsa-ro, Gangnam-gu, Seoul, 06097, Republic of Korea
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Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

8. Conclusion [21 CFR 807.92(b)(3)]

In conclusion, the tests conducted, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of AutoSeg-H meet applicable requirements and standards for the safety and effectiveness of the device for its intended use. There are some differences in technological characteristics between the predicates and proposed device, but those differences do not raise new or different questions of safety or effectiveness as compared to the predicate devices. Therefore, AutoSeg-H is substantially equivalent to the currently marketed predicate device.