August 11, 2022

Hangzhou Deepwise & league of PHD Technology Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
CHINA

Re: K220910
Trade/Device Name: Medical image processing software
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: July 7, 2022
Received: July 11, 2022

Dear Ray Wang:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: 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)*
K220910

Device Name
Medical image processing software

Indications for Use *(Describe)*
The DW-CACTAS is a medical image processing software, combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection(MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), this software is used for post-processing of coronary CT angiography 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.

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

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The assigned 510(k) Number: K220910

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K220910

1. Date of Preparation: 08/10/2022

2. Sponsor

Hangzhou Deepwise & league of PHD Technology Co.,Ltd.
Room 705, Building 8, 1818-2 Wenyi West Road, Yuhang District, 311121, Hangzhou City, Zhejiang Province, China
Contact Person: Hailong Xu
Position: QA manager
Tel: +86-13521047585
Fax: +86-0571-88075727
Email: xuhailong@deepwise.com

3. Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China,102401
Contact Person: Ray Wang
Position: General Manager
Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

4. Proposed Device Identification

Trade Name: Medical image processing software
Common Name: System, X-Ray, Tomography, Computed
Regulatory Information:
Classification: II
Product Code: JAK
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Review Panel: Radiology

Indication For Use Statement:
The DW-CACTAS is a medical image processing software, combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection(MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), this software is used for post-processing of coronary CT angiography images.

5. Predicate Device Identification

510(k) Number: K173637
Product Name: Syngo.CT Coronary Analysis
Manufacturer: Siemens Medical Solutions USA, Inc.

6. Device Description

Medical image processing software (DW- CACTAS) is a network system management and image processing software based on local storage service. The software obtains image data from medical image equipment through image network transmission and storage technology, and stores data in the server. Through the information system management function module and image processing module, medical institution can transmit, store, query, browse, manage and process image data.

Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection(MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), the DW- CACTAS is used for post-processing of coronary CT angiography images.

The data transmission of the software follows the HTTP transmission protocol and DICOM network protocol, and supports the DICOM3.0 standard data transmission interface.
The medical image storage format is DICOM.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- Bench Testing for the Software Test Report
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

ITEM	Proposed Device Medical image processing software	Predicate Device K173637 syngo.CT Coronary Analysis	Remark
Software Operating Platform	Linux Ubuntu 16.04	SOMARIS/8 VB30	Analysis 1
Indications for Use	The DW-CACTAS is a medical image processing software, combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection(MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), this software is used for post-processing of coronary CT angiography images.	syngo.CT Coronary Analysis is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets. Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), evaluation tools (coronary vessel centerline calculation, stenosis calculation and plaque analysis) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified coronary lesions and evaluation, documentation and follow-up of any such lesion. These visualization/evaluation tools allow for characterization (geometry (length, lumen diameter, cross section area, stenosis grade) and appearance (HU values)) of coronary lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.	SAME
Visualization and	Image List	Basic Visualization and Navigation	Analysis 2

Segmentation Tools		Tools	
	Myocardium segmentation in VR image	Automatic Organ Segmentation	
	Blood vessel centerline calculation	Automatic Vessel Tracing	
	3D VR image of Image browsing and processing functions	3D Vessel Visualization Tools	
	2D VR image of Image browsing and processing functions	2D Vessel Visualization Tools	
	Blood vessel positioning	Vessel Navigation Tools	
	Blood vessel identification	Vessel Definition Tools	
	Blood vessel measurement and centerline calculation	Vessel Evaluation Tools	
	VR/CPR/lumen/Xsection image creation	Result Image Creation	
	/	Integrated Reporting	Analysis 3
Archiving and Reporting	User Interface	User Interface	SAME
	Archiving/Storing	Archiving/Storing	SAME
	Communication	Communication	SAME

Analysis 1:
The proposed device is different with the predicate device on Software Operating Platform, but the intended use is the same, for this risk we have conducted the software testing, the test results show that our products can meet the intended use and the difference does not raise any risk.

Analysis 2:
We are not sure whether the proposed device and the predicate device are exactly the same on Visualization and Segmentation Tools, because we can't get the algorithm for predicate device, but the intended use is the same. For this uncertain deficiency we have conducted the software testing, the test results show that our products can meet the intended use, and compared to the predicate, the uncertain deficiency does not raise any risk.

Analysis 3:
The proposed device is different with the predicate device on Visualization and Segmentation Tools, the proposed device won’t generate report, but this difference would not affect its safety and effectiveness. The proposed device is used by professionals with medical imaging diagnosis experience, according to the medical imaging experience of professionals, combined with the patient's medical history and the patient's own physical condition for diagnosis. The proposed device has better performance to the predicate device. Both proposed device and predicate device are safe and effective, so we consider which is same with the predicate device and this difference does not raise any risk.

10. Performance Data

Non-Clinical Testing Summary

Non-clinical tests (integration and functional) were conducted for DW- CACTAS during product development. Performance tests were conducted to test the functionality of DW- CACTAS. The modifications described in this Premarket Notification were supported with verification/validation testing. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence. Hangzhou Deepwise & league of PHD Technology Co.,Ltd. claims conformance to the following performance standards:

Product Area	Title of Standard	Publication Date	Standards Development Organization
Radiology	NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set	06/27/2016	NEMA
Software	IEC 62304 Edition 1.1 Medical device software - Software life cycle processes	2015-06	IEC
Software/ Informatics	Medical devices - Application of risk management to medical devices	2019-12	ISO
General I (QS/RM)	IEC 62366-1 Edition 1.1 Medical devices - Part 1: Application of usability engineering to medical devices	2020-06	IEC

Non-Clinical Performance (Bench) Testing

The function of the software meets the expected functional requirements. According to the DICOM standard communication protocol, it establishes a communication connection with the PACS system, obtains medical image data through network communication, and can realize the transmission, browsing, query and processing of medical images.

Software Verification and Validation

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation support the claim of substantial equivalence.

Medical image processing software conforms to the Cybersecurity requirements by implementing a

process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014" is included within this submission.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. Medical image processing software is designed to fulfill the requirements of the applicable safety and performance standards as listed above.

11. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.