DDE MRI Solutions LTD
% John J. Smith, M.D, J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
WASHINGTON DC 20004

December 15, 2021

Re: K211039
Trade/Device Name: BIT-Motion
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 20, 2021
Received: October 20, 2021

Dear John Smith:

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.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K211039

Device Name
BIT-Motion

Indications for Use *(Describe)*
The BIT-Motion is a stand-alone image post processing software. The Bit-Motion is intended for use as a PACS device, which is interfaced to the clinics' LAN. It receives clinical studies from hospital modalities, processes functional volumetric data and generates parametric maps that display changes in image intensity. It also includes manual display manipulation, annotation and control tools, which assist professional users to evaluate the displayed maps and to transfer the results to the PACS, in DICOM format.

The BIT-Motion indications for use are receiving breast studies from MRI scanners and processing them to generate DTI (Diffusion Tensor Imaging) 2D and 3D parametric maps that display changes in the values of water diffusion coefficients and directions, as well as in indices defining diffusion anisotropy. The device-displayed DTI parametric maps are evaluated by the users. The device is indicated for use by trained radiologists and may provide information on breast water diffusion features. The BIT-Motion should not be used in isolation for evaluating breast tissue features or for making patient management decisions.

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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510(k) Summary of Safety and Effectiveness

Submitter details

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Date Prepared: December 15, 2021

Details of the submitted Device

Proprietary Name:	BIT-Motion
Regulation Number	892.2050
Product Code:	LLZ
Committee/Panel:	Radiology
Device Class:	II

Type of 510(k) Submission:

Traditional

Identification of the Legally Marketed Predicate Device

CADstream Version 4.0 (K043216) Manufactured by Confirma, INC

Device Description

The BIT-Motion is a software package that is aimed to process MRI images. The software runs on a PC server, which is connected to the Local Area Network (LAN). The device receives MRI datasets from MRI scanner over the network in DICOM format, processes the images and transfers the outcome images in DICOM format, to selected PCAS stations.

Intended use and indications for Use

The BIT-Motion is a stand-alone image post processing software. The Bit-Motion is intended for use as a PACS device, which is interfaced to the clinics' LAN. It receives clinical studies from hospital modalities, processes functional volumetric data and generates parametric maps that display changes in image intensity. It also includes manual display manipulation, annotation and control tools, which assist professional users to evaluate the displayed maps and to transfer the results to the PACS, in DICOM format.

The BIT-Motion indications for use are receiving breast studies from MRI scanners and processing them to generate DTI (Diffusion Tensor Imaging) 2D and 3D parametric maps that display changes in the values of water diffusion coefficients and directions, as well as in indices defining diffusion anisotropy. The device-displayed DTI parametric maps are evaluated by the users. The device is indicated for use by trained radiologists and may provide information on breast water diffusion features. The BIT-Motion should not be used in isolation for evaluating breast tissue features or for making patient management decisions.

Technological Characteristics

The BIT-Motion software package is installed in an off-the-shelf PC server, which include Man Machine Interface (standard screen, keyboard and mouse). The Operating System is Microsoft W10. The software package consists of the following software modules: The Communication, User Interface, Algorithm, and graphical tools. Data inputs and output are MRI studies in DICOM format.

Performance Tests

Non-Clinical tests

Conforming to 21CFR820.30(f) requirements, the device software has been verified by testing the software following predefined software test plan.

In addition, the device performance has been verified, by testing it using MRI dedicated phantom.

Conforming to 21CFR820.30(g) requirements, the device performance, usability and reliability have been validated by testing the device in end-user environment.

The above testing methods adhered to state-of-art standards and procedures. The tests' results demonstrate that the device output meet the design input and the intended use.

Risk Management

The device risks were managed and controlled following the requirements of ISO 14971standard. The device hazards were identified, their risk levels were evaluated and mitigation measures were taken to reduce the risk levels. In DDE opinion the benefits of the BIT-Motion outcome, overweight the device residual risks.

Substantial Equivalence

Comparison with the predicate device

Parameter	Predicate Device CADstream Version 4.0 (K043216)	Subject Device BIT-Motion
Intended use	*A post processing software, which is intended to receive clinical studies from hospital modalities, to process image volumetric data, to generate images that display changes in image intensity. It also includes manual display manipulation and annotation tools, which assist professional user to evaluate the maps. The device is interfaced with the hospital PACS devices to transfer the processing results in DICOM format.*	The same
21CFR section	892.2050	The same
Product Code	LLZ	The same

Indications for use	*When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made based solely on the results of the device analysis*	Very Similar Difference: The BIT-Motion indications for use do not include screening and diagnosis.
Technological Characteristics		
Device nature	Post processing SW package	The same
Data inputs	MRI images in DICOM format	The same
SW processing algorithm	*The predicated algorithm is designed to analyze dynamic breast MRI studies to provide DCE parametric maps*	Difference: The BIT-Motion algorithm is designed to analyze contrast free pre-defined breast MRI studies to provides DTI parametric maps
SW controls (Communication, processing, User interface)	Carestream Health, Inc unique SW Design	Difference: DDE MRI Solutions Ltd. unique SW Design
Data outputs	MRI images in DICOM format	The same

Substantial Equivalence conclusion

The BIT-Motion has the same intended use and very similar indication for use as the legally marketed predicate device. The two devices have similar technological characteristics. Results of tests, which were adhered to state-of-art standards and procedures, demonstrate that differences in the technological characteristics do not raise new questions of safety or effectiveness. Based on this discussion, it is DDE's opinion that BIT-Motion is substantially equivalent in terms of safety and effectiveness to the CADstream Version 4.0 (K043216) predicate device.