November 16, 2022

MRIguidance B.V.
℅ Sujith Shetty
Executive Vice President
MAXIS Medical
3031 Tisch Way, Suite 1010
SAN JOSE CA 95128

Re: K221762
Trade/Device Name: BoneMRI v1.4
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: October 7, 2022
Received: October 11, 2022

Dear Sujith Shetty:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*
K221762

Device Name
BoneMRI V1.4

Indications for Use *(Describe)*
BoneMRI is an image processing software that can be used for image enhancement in MRI images. It can be used to visualize the bone structures in MRI images with enhanced contrast with respect to the surrounding soft tissue. It is to be used in the pelvic region, which includes the bony anatomy of the sacrum, hip bones and femoral heads; and the lumbar spine region, which includes the bony anatomy of the vertebrae from L3 to S1. BoneMRI is not to be used for diagnosis or monitoring of (primary or metastatic) tumors.

Warning: BoneMRI images are not intended to replace CT 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.

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:

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"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."

510(K) SUMMARY

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

510 (k) number: K221762

Applicant Information

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Date Prepared: December 22, 2021

Official Correspondent

Dr. Sujith Shetty
Executive Vice President
MAXIS LLC
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Device Information

Trade Name:	BoneMRI application
Common Name:	MRI image enhancement software
Classification name:	Medical image management and processing system (21CRF892.2050)
Regulatory Class:	Class II
Product Code:	QIH

Predicate Device

Table 5-1 Predicate Device – BoneMRI v1.2

Name	Manufacturer	510(k)#
BoneMRI v1.2	MRIguidance B.V.	K202404

This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

Device Description

The BoneMRI application is a standalone image processing software application that analyses 3D gradient echo MRI scans acquired with a dedicated MRI scan protocol. From the analysis, 3D tomographic radiodensity contrast images, called BoneMRI images, are constructed.

The BoneMRI images can be used to visualize the bone structures in MR images with enhanced contrast with respect to the surrounding soft tissue. The application is designed to be used by imaging experts, such as radiologists or orthopedic surgeons, typically in a physician's office.

The BoneMRI application is a server application running in the clinic or hospital networks. It returns the reconstructed BoneMRI images as DICOM images. The application uses an algorithm to detect bone images from MRIs obtained using a specific acquisition sequence. The algorithm training sets included information from multiple clinical sites, multiple anatomies and multiple scanners to ensure that the trained algorithm was robust with respect to the approved indications for use. None of the data used in the training dataset was used subsequently in the validation dataset.

Indications for Use

BoneMRI is an image processing software that can be used for image enhancement in MRI images. It can be used to visualize the bone structures in MRI images with enhanced contrast with respect to the surrounding soft tissue. It is to be used in the pelvic region, which includes the bony anatomy of the sacrum, hip bones, and femoral heads; and the lumbar spine region, which includes the bony anatomy of the vertebrae from L3 to S1. BoneMRI is not to be used for diagnosis or monitoring of (primary or metastatic) tumors.

Warning: BoneMRI images are not intended to replace CT images.

Comparison of Technological Characteristics with the Predicate Device:

A comparison of the intended use, indication for use, and technological characteristics of the BoneMRI v1.4 application to the predicate device, BoneMRI v1.2, is presented below. We have included the attributes suggested in FDA's website guidance for this comparison.

A. Intended Use

	Predicate Device BoneMRI v1.2	**Subject Device BoneMRI v1.4**	**Comment**
Indications for Use	BoneMRI is an image processing software that can be used for image enhancement in MRI images. It can be used to visualize the bone structures in MRI images with enhanced contrast with respect to the	BoneMRI is an image processing software that can be used for image enhancement in MRI images. It can be used to visualize the bone structures in MRI images with enhanced contrast with respect to the	Similar – BoneMRI v1.4 has an expanded indications for use including the boney structures of the lumbar spine.

	Predicate Device BoneMRI v1.2	Subject Device BoneMRI v1.4	Comment
	surrounding soft tissue. It is to be used in the pelvic region, which includes the boney anatomy of the sacrum, hip bones and femoral heads. Warning: BoneMRI images are not intended to replace CT images and are not to be used for diagnosis or monitoring of (primary or metastatic) tumors.	surrounding soft tissue. It is to be used in the pelvic region, which includes the bony anatomy of the sacrum, hip bones and femoral heads; and the lumbar spine region, which includes the bony anatomy of the vertebrae from L3 to S1. BoneMRI is not to be used for diagnosis or monitoring of (primary or metastatic) tumors. Warning: BoneMRI images are not intended to replace CT images	
21CFR Section	892.2050	892.2050	The same
Product Code	QIH	QIH	The same
Target Population	Adults	Adults	The same

B. Technological Characteristics

	Predicate Device BoneMRI v1.2	Subject Device BoneMRI v1.4	Comment
Device Nature	Software package	Software package	The same
Operating System	Linux	Linux	The same
Data input	MRI images in DICOM format	MRI images in DICOM format	The same

	Predicate Device BoneMRI v1.2	Subject Device BoneMRI v1.4	Comment
Data output	MRI images in DICOM format	MRI images in DICOM format	The same
Processing Algorithms	MRIguidance software implements an image enhancement algorithm using convolutional neural network. Original images are enhanced by running them through a cascade of filter banks, where thresholding and scaling operations are applied. Separate neural network-based filters are obtained to assign a Hounsfield Unit (HU) value to a single volume element, based on intensity and contextual information. The parameters of the model were obtained through an algorithm development pipeline.	MRIguidance software implements an image enhancement algorithm using convolutional neural network. Original images are enhanced by running them through a cascade of filter banks, where thresholding and scaling operations are applied. Separate neural network-based filters are obtained to assign a Hounsfield Unit (HU) value to a single volume element, based on intensity and contextual information. The parameters of the model were obtained through an algorithm development pipeline.	The same
User Interface	None – enhanced images are viewed on existing PACS workstations	None – enhanced images are viewed on existing PACS workstations	The same

	Predicate Device BoneMRI v1.2	Subject Device BoneMRI v1.4	Comment
Workflow	The software operates on DICOM files on the file system, enhances the images, and stores the enhanced images on the file system. The receipt of original DICOM image files and delivery of enhanced images as DICOM files depends on other software systems. Enhanced images co-exist with the original images.	The software operates on DICOM files on the file system, enhances the images, and stores the enhanced images on the file system. The receipt of original DICOM image files and delivery of enhanced images as DICOM files depends on other software systems. Enhanced images co-exist with the original images.	The same

Performance Data:

Previous performance testing to verify and validate the software of BoneMRI v1.2 for the pelvic and hip region was submitted and approved under K202404.

BoneMRI conducted the following performance testing:

1. Software verification and validation testing
2. Studies that utilized retrospective clinical data to demonstrate the software enhanced imaging quality in MR images via an enhancement of bone.

BoneMRI Lumbar spine region – Voxel-by-Voxel analysis

A quantitative voxel-by-voxel validation of BoneMRI was performed on imaging data from 73 patients. The demographics of the patient population is described in the table below.

Validation data demographics	
Number of patients	73
Indications	sacroiliitis, degenerative spine and pelvic diseases, spondylolisthesis, radiculopathy, spondylosis and spinal fractures
Gender	Male: 48% Female: 52%
Age	50 ± 15 years
Data origin/Ethnicity	Europe Asia

The imaging data consists of the BoneMRI and a standard CT of the same patient in the same anatomical region, acquired during previously conducted clinical investigations. The validations were conducted by MRIguidance based on an algorithm to detect bone images from MRIs obtained using a specific acquisition sequence.

Training and test datasets were selected and maintained to be appropriately independent of one another. All training and validation activities were recorded to ensure independence. In addition, validation was performed on data from independent sites (cross-site validation) to ensure that validation was performed on data from unseen centers.

The objective was to validate the quantitative accuracy of BoneMRI for the lumbar spine region using rigorous, objective, and unbiased statistical tests comparing bone morphology, radiodensity, and radiodensity contrast in BoneMRI and CT images. Therefore, the endpoints of this testing were the metrics that described the accuracy of 3D bone morphology, radiodensity, and radiodensity contrast versus co-registered CT scans (reference standard) in terms of voxel-by-voxel HUs and standard deviations around these HU values.

The results from the validation testing were compared to the accuracy acceptance criteria, specified below, and were found to fall within the pre-specified acceptance criteria ($p<0.05$).

The results demonstrate clinically acceptable accuracy on each of these endpoints.

The data provided demonstrate that BoneMRI application can

- accurately reconstruct the 3D bone morphology with a mean absolute cortical delineation error below 1.0 mm on average;
- accurately reconstructs the tissue radiodensity, with a mean deviation below 25 HU on average and a mean deviation below 55 HU specifically for bone;
- accurately reconstructs the tissue radiodensity contrast, with a mean HU correlation coefficient above 0.75 specifically for bone.

CONCLUSION: BoneMRI demonstrates accurate bone morphology, radiodensity, and radiodensity contrast. Thus, BoneMRI is a useful tool to qualitatively and quantitatively assess the lumbar spine region.

Conclusions:

BoneMRI v1.4, based on the indications for use, product performance, and clinical information provided in this notification, has been shown to be substantially equivalent to the currently marketed predicate device, its predecessor, BoneMRI v1.2. The two devices have the same technological characteristics: both algorithms use the same image-based reconstruction, and both methods have optimized parameters to ensure the robustness of the algorithm. This 510(k) submission includes information on the BoneMRI v1.4 technological characteristics, as well as performance data and verification and validation activities demonstrating that BoneMRI is as safe and effective as the predicate. This evaluation did not raise any new issues pertaining to safety or effectiveness.