



February 22, 2023

MRIGuidance B.V.  
% Sujith Shetty  
Executive Vice President  
MAXIS Medical  
3031 Tisch Way, Suite 1010  
San Jose, California 95128

Re: K230197

Trade/Device Name: BoneMRI v1.6  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical Image Management And Processing System  
Regulatory Class: Class II  
Product Code: QIH  
Dated: January 25, 2023  
Received: January 25, 2023

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/pmnmn.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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.  
Assistant Director  
Magnetic Resonance and Nuclear Medicine Team  
DHT8C: Division of Radiological Imaging  
and Radiation Therapy Devices  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K230197

Device Name

BoneMRI v1.6

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.\***

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## 5.1 510(k) Summary

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

**5.2 510(k) number:** K230197

## 5.3 Applicant Information

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## 5.4 Contact Person

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Date Prepared: January 27, 2023

## 5.5 Official Correspondent

Dr. Sujith Shetty  
Executive Vice President  
MAXIS LLC  
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## 5.6 Device Information

Trade Name:	BoneMRI v1.6
Common Name:	MRI image enhancement software
Classification Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Regulatory Class:	Class II
Product Code:	QIH

## 5.7 Predicate Device

Name	Manufacturer	510(k)#
BoneMRI v1.4	MRIguidance B.V.	K221762

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

## 5.8 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 on the clinic or hospital networks. It is available as fully on-premise software with specific GPU hardware requirements, or partly running as a managed service, for which the environment in which the managed modules run is controlled by MRIguidance, but the managed service will not receive protected health information (PHI). Within the hospital network, the application communicates with a DICOM compatible imaging archive (e.g., a PACS) to receive input MRI and to return BoneMRI images. Reading of the resulting BoneMRI images is performed using regular DICOM compatible medical imaging viewing software.

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.

## 5.9 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.

**5.10 Comparison of Technological Characteristics with the Predicate Device:**

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

**A. Intended Use**

	<b>Predicate Device BoneMRI v1.4</b>	<b>Subject Device BoneMRI</b>	<b>Comment</b>
Intended Use	<p>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.</p> <p>Warning: BoneMRI images are not intended to replace CT images.</p>	<p>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.</p> <p>Warning: BoneMRI images are not intended to replace CT images.</p>	The same
21CFR Section	892.2050	892.2050	The same
Product Code	QIH	QIH	The same



	<b>Predicate Device BoneMRI v1.4</b>	<b>Subject Device BoneMRI</b>	<b>Comment</b>
Target Population	Adults	Adults	The same

**B. Technological Characteristics**

	<b>Predicate Device BoneMRI v1.4</b>	<b>Subject Device BoneMRI</b>	<b>Comment</b>
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
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
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	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	The same

	<b>Predicate Device BoneMRI v1.4</b>	<b>Subject Device BoneMRI</b>	<b>Comment</b>
	depends on other software systems. Enhanced images co-exist with the original images.	depends on other software systems. Enhanced images co-exist with the original images.	

**5.11 Performance Data:**

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.

**Software verification and validation testing**

Software verification and validation testing were conducted, 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,” dated May 11, 2005.

**Performance validation**

A quantitative voxel-by-voxel validation of BoneMRI was performed on imaging data from 101 and 103 patients for the pelvic region and lumbar spine region, respectively. The demographics of the patient population are described in the table below.

<b>Validation data demographics</b>		
<b>Anatomy</b>	Pelvic region	Lumbar spine region
<b>Number of patients</b>	101	103
<b>Indications</b>	Sacroiliitis, developmental hip dysplasia, avascular necrosis of femoral head and femoral acetabular impingement.	Sacroiliitis, degenerative spine diseases, spondylolisthesis, radiculopathy, spondylosis and spinal fractures.
<b>Gender</b>	Male: 73 Female: 28	Male: 49 Female: 54
<b>Age</b>	52 ± 21 years	55 ± 15 years
<b>Data origin/Ethnicity</b>	USA, Europe, Asia	USA, Europe, Asia



The imaging data consist of the BoneMRI and CT images from the same patient in the same anatomical region, acquired during previously conducted clinical investigations. The validations were conducted by MRIfguidance based on an algorithm to detect bone images from MRIs obtained using a specific 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 centers that did not provide training data.

The objective was to validate the quantitative accuracy of BoneMRI for the pelvic region and 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 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 pelvic region and the lumbar spine region.

**5.12 Conclusions:**

The BoneMRI application, based on the indications for use, product performance, and clinical information provided in this notification, have been shown to be substantially equivalent to the currently marketed predicate device, its predecessor, BoneMRI v1.4. 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 Special 510(k) submission includes information on the BoneMRI technological characteristics, as well as performance data and verification and validation activities demonstrating that BoneMRI is as safe and effective as the predicate and does not raise different questions of safety or effectiveness.