MRIguidance B.V
℅ Suji Shetty
Executive Vice President
Maxis Medical
7052 Hollow Lake Way
San Jose, California 95120

December 22, 2021

Re: K202404
Trade/Device Name: BoneMRI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 29, 2021
Received: November 30, 2021

Dear Suji 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,

Jessica Lamb, Ph.D.
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202404

Device Name
BoneMRI

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 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.

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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5.0 510(K) STATEMENT/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: K202404

I. Applicant Information

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Date Prepared: December 22, 2021

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II. Device Information

Trade Name:	BoneMRI
Common Name:	MRI image enhancement software
Classification name:	Picture archiving and Communication system (21CRF892.2050)
Regulatory Class:	Class II
Product Code:	QIH

III. Predicate Device

Name	Manufacturer	510(k)#
SubtleMR	Subtle Medical, Inc.	K191688

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

IV. 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 orthopaedic 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.

V. 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 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.

VI. 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 SubtleMR are presented below. We have included the attributes suggested in FDA's website guidance for this comparison.

Name	Manufacturer	510(k)#
SubtleMR	Subtle Medical, Inc.	K191688

A. Intended Use

	Predicate Device SubtleMR	Subject Device BoneMRI	Comment
Intended Use	SubtleMR is an image processing software that can be used for image enhancement in MRI images. It can be used to reduce image noise for head, spine, neck, and knee MRI, or increase image sharpness for non-contrast-enhanced head MRI.	BoneMRI is an image processing software that can be used for image enhancement in MR images. It can be used to visualize the bone structures in MR images with enhanced contrast with respect to the surrounding soft tissue	Similar – Intended uses are the same for Image enhancements for MRI. But the intended use differences does not affect the safety and effectiveness of the device when used as labeled and is similar to the predicate use.
21CFR Section	892.2050	892.2050	The same
Product Code	LLZ	QIH	Similar
Target Population	Adults	Adults	The same

B. Technological Characteristics

	Predicate Device SubtleMR	Subject Device BoneMRI	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
Data output	MRI images in DICOM format	MRI images in DICOM format	The same
Processing Algorithms	SubtleMR software implements an image enhancement algorithm using convolutional neural network based filtering. Original images are enhanced by running through a cascade of filter	MRIguidance software implements an image enhancement algorithm using convolutional neural network. Original images are enhanced by running them through a cascade of	Different – The algorithm while using similar methodology, uses different filters and outputs to enhance the image. The difference does not affect the safety and

	Predicate Device SubtleMR	Subject Device BoneMRI	Comment
	banks, where thresholding and scaling operations are applied. Separate neural network based filters are obtained for noise reduction and sharpness increase. The parameters of the filters were obtained through an image guided optimization process.	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.	effectiveness of the device when used as labeled and is similar to the predicate use.
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 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

VII. 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.

BoneMRI Pelvic region – Voxel-by-Voxel analysis

Quantitative voxel-by-voxel validation of BoneMRI was performed on imaging data from 61 patients, consisting of the BoneMRI and CT of the same patient, acquired during the previously conducted clinical investigations. MRIguidance conducted the validations based on an in-house developed algorithm validation pipeline, the core validation framework. The objective was to validate the quantitative accuracy of BoneMRI for the pelvic region using rigorous, objective, and unbiased statistical tests. The endpoints 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 demonstrate clinically acceptable accuracy on all of the endpoints.

The data provided demonstrate that BoneMRI application v1.2 can accurately reconstruct the 3D bone morphology with a mean absolute cortical delineation error below 1.0 mm on average; accurately reconstruct the tissue radiodensity with a mean deviation below 10 HU on average and a mean deviation below 55 HU for bone specifically; accurately reconstruct the tissue radiodensity contrast with a mean HU correlation coefficient above 0.80 on average and a mean HU correlation coefficient above 0.75 for bone specifically.

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

VIII. Conclusions:

BoneMRI, based on the indications for use, product performance, and clinical information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device. The two devices have similar technological characteristics: both algorithms use 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 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 and effectiveness.