August 21, 2026

Mriguidance B.V.
% Sam Engleman
Consultant
Avania CRO Canada
250 Carlaw Ave., Suite 108
Toronto, ON M4M 3L1
Canada

Re: K260584
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: July 20, 2026
Received: July 20, 2026

Dear Sam Engleman:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device

Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260584

Please provide the device trade name(s).

BoneMRI

Please provide your Indications for Use below.

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 increased contrast with respect to the surrounding soft tissue in BoneMRI images and to visualize the T1w contrast in Synthetic T1w images. It is to be used in the pelvic region, which includes the bony anatomy of the sacrum, hip bones and femoral heads; and the spine, which includes the bony anatomy of the cervical, thoracic, lumbar, and S1 vertebrae. BoneMRI is indicated for use in patients 12 years and older. Synthetic T1w is indicated for use in patients 18 years and older.

BoneMRI is not to be used for diagnosis or monitoring of (primary or metastatic) tumors. BoneMRI images are not intended to replace CT images in general but can be used to visualize 3D bone morphology, tissue radiodensity and tissue radiodensity contrast.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

MRI guidance

K260584

510(k) Summary

1. 510(k) Information

510(k) Number	K260584
Date prepared	August 17, 2026
510(k) Submitter	MRIguidance B.V. Maliesingel 23, 3581 BG Utrecht, the Netherlands
510(k) Submitter Contact Person	Marijn van Stralen Chief Technology Officer MRIguidance B.V. Email: prrc@mriguidance.com Tel: +31 681741711
Correspondent Contact Person	Sam Engelman Avania CRO Canada 250 Carlaw Avenue, Suite # 108, Toronto, Ontario M4M 3L1, Canada Email: regulatory@avaniaclinical.com Tel: +1 647-878-9951

2. Device information

Device Trade Name	BoneMRI
Device Common Name	MRI image enhancement software
Device Classification Name	Medical image management and processing system (21 CFR 892.2050)
Device Classification	Class II
Product Code	QIH

3. Predicate Device

Device Trade Name	BoneMRI
Manufacturer	MRIguidance B.V.
Device 510(k) Clearance	K233030
Device Classification Name	Medical image management and processing system (21 CFR 892.2050)
Device Classification	Class II
Product Code	QIH

4. 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 of the gradient echo MRI scan, 3D tomographic radiodensity contrast images, called BoneMRI images, are constructed.

The BoneMRI application is a server application running on the clinic or hospital networks. It is available as a managed cloud service, for which the environment in which the managed modules run is controlled by MRIguidance. All data sent to the managed cloud server will be de-identified before it leaves the clinic or hospital network, and as such, the managed cloud service will not receive 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 image viewing software.

Like the proposed predicate device, the BoneMRI application uses an algorithm to detect bone images from MRIs obtained using a specific gradient echo acquisition sequence. The algorithm training sets included images 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.

Additionally, BoneMRI v.2.0.0 introduces a feature to visualize T1w contrast in Synthetic T1w images of the spine region acquired for patients aged 18 years and older.

5. 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 increased contrast with respect to the surrounding soft tissue in BoneMRI images and to visualise the T1w contrast in Synthetic T1w images.

It is to be used in the pelvic region, which includes the bony anatomy of the sacrum, hip bones and femoral heads; and the spine, which includes the bony anatomy of the cervical, thoracic, lumbar, and S1 vertebrae. BoneMRI is indicated for use in patients 12 years and older. Synthetic T1w is indicated for use in patients 18 years and older.

BoneMRI is not to be used for diagnosis or monitoring of (primary or metastatic) tumors. BoneMRI images are not intended to replace CT images in general but can be used to visualize 3D bone morphology, tissue radiodensity and tissue radiodensity contrast.

6. Comparison of Technological Characteristics with the Predicate Device

A comparison of the intended use, indication for use, and technological characteristics of the subject BoneMRI application to the predicate device (BoneMRI v1.7, K233030) is presented below. We have included the attributes suggested in the July 2018 Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" for this comparison.

	Predicate Deice (BoneMRI v1.7; K233030)	Subject Device (BoneMRI v.2.0.0)	Comment
Intended 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.	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.	**The same.** The subject device and the proposed predicate devices use artificial intelligence-based algorithms to generate contrasts to visualize bone structures in previously acquired T1-weighted MRI images.

	Predicate Deice (BoneMRI v1.7; K233030)	Subject Device (BoneMRI v.2.0.0)	Comment
21CFR Section	829.2050	829.2050	**The same.**
Product Code	QIH	QIH	**The same.**
Target Population	Adolescents (>12 years of age) and adults.	For BoneMRI images: Adolescents (>12 years of age) and adults For Synthetic T1w images: Adolescents (> 18 years of age) and adults	**The same** for BoneMRI v.2.0.0 and BoneMRI v1.7 for the generation of BoneMRI images from source MR images of the spine and pelvic region. Synthetic T1w images are generated for patients aged 18 years from source MR images of the spine region. Thus, the intended patient population for Synthetic T1w images is a subset of that for BoneMRI images. BoneMRI v2.0.0 software does not generate Synthetic T1w images for patients <18 years of age and for pelvic images. This risk control measure against potential un-intended use of the Synthetic T1w ML-DSF in the wrong patient population, is implemented by design.
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 increased 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 spine, which includes the bony anatomy of the cervical,	**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 increased contrast with respect to the surrounding soft tissue in BoneMRI images **and to visualise the T1w contrast in Synthetic T1w images.** It is to be used in the pelvic region, which includes the bony	**Comparable.** The indications for use of the BoneMRI v1.7 are being updated in BoneMRI v.2.0.0 to reflect the ability to visualize contrast in Synthetic T1 images. A Synthetic T1w image, like a BoneMRI image is generated by enhancing the same source image-dual-echo gradient MR image. This update does not raise new or different questions of safety and

	Predicate Deice (BoneMRI v1.7; K233030)	Subject Device (BoneMRI v.2.0.0)	Comment
	thoracic, lumbar, and S1 vertebrae. BoneMRI is indicated for use in patients 12 years and older. BoneMRI is not to be used for diagnosis or monitoring of (primary or metastatic) tumors. BoneMRI images are not intended to replace CT images in general but can be used to visualize 3D bone morphology, tissue radiodensity and tissue radiodensity contrast.	anatomy of the sacrum, hip bones and femoral heads; and the spine, which includes the bony anatomy of the cervical, thoracic, lumbar, and S1 vertebrae. BoneMRI is indicated for use in patients 12 years and older. Synthetic T1w is indicated for use in patients 18 years and older. BoneMRI is not to be used for diagnosis or monitoring of (primary or metastatic) tumors. BoneMRI images are not intended to replace CT images in general but can be used to visualize 3D bone morphology, tissue radiodensity and tissue radiodensity contrast.	effectiveness in the subject device.

7. Summary of Changes

The subject BoneMRI application v.2.0.0 has the same intended use and a similar indication as the identified predicate device, its predecessor (BoneMRI v1.7, K233030). The technological features of the BoneMRI v.2.0.0 are identical to those as the predicate device except for the addition of the feature to visualize contrast in synthetic T1w images. Risk analysis and performance testing of the BoneMRI application demonstrate that the features of the device do not raise new safety or effectiveness questions compared to the predicate device.

Additionally, while BoneMRI v1.7 had the option to be deployed on-premise or to be hosted on the MRIguidance cloud server, BoneMRI v.2.0.0 will now always be hosted on the MRIguidance cloud server without the option to host the application on a local hospital server. BoneMRI v.2.0.0 also includes an API which allows BoneMRI cloud solution to securely connect to the Siemens Teamplay Digital platform as an external "gateway", which allows the exchange of images between a hospital and BoneMRI cloud, providing that there is a data exchange agreement between the two parties.

The BoneMRI application has been updated since its FDA clearance under 510(k) K233030, within the scope of the FDA cleared pre-determined change control plan (PCCP). A modification to this PCCP is included to allow for updates to the Synthetic T1w ML-DSF in the future.

We conclude that the BoneMRI application is substantially equivalent to the identified predicate devices.

8. Predetermined Change Control Plan

The BoneMRI application uses algorithms derived from machine learning (ML) to detect bone images from MRIs obtained using a specific gradient echo acquisition sequence and to generate T1w contrast images. The algorithm training sets included images 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.

MRIguidance will make future algorithm improvements under a Predetermined Change Control Plan (PCCP). In that plan, a protocol is provided to mitigate the risks of the algorithm changes leading to changes in the device's technical specifications or negatively affecting performance specifications directly associated with the indications for use of the device. Changes made under this PCCP are detailed in the table below. In accordance with the PCCP, all algorithm modifications will be trained, tuned, and locked prior to release of the application.

Modification	Rationale
1. Re-training to improve ML model performance with additional training data	Re-training of the ML model with additional data to increase the safety and performance of the device in any of the following Categories: • Increased accuracy; • Increased performance for challenging cases such as rare pathologies or artifacts; • Increased robustness and generalization of the model.
2. Validation of additional scanner support	Validation of the ML model (either with or without additional retraining of the ML model) in order to validate an additional MRI vendor or field strength.
3. Validation of Synthetic T1w anatomical regions for which the BoneMRI image ML model already has been validated	Validation of the ML model (either with or without additional retraining of the ML model) in order to extend Synthetic T1w anatomical region support.

With any modification, the algorithms will be validated using the existing testing methods, to meet the existing performance criteria (see section 9.2).
Such updates will not allow for a negative impact of the existing performance. For any software update, users will be informed prior to the update to be installed.

9. Performance Data

9.1. 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 June 14, 2023.

9.2. Performance Validation

Similar to the predicate device, quantitative voxel-by-voxel validation of BoneMRI was performed on imaging data from the spine and pelvic region of patients 12 years and older.

The following performance criteria were tested in comparison to conventional CT and T1w imaging, for BoneMRI and Synthetic T1w images respectively.

For BoneMRI images

- *Surface distance*: BoneMRI accurately reconstructs the 3D bone morphology with a mean absolute cortical delineation error below 1.0 mm on average
- *Voxelwise error*: BoneMRI accurately reconstructs the tissue radiodensity, with a mean deviation below 25 HU on average and a mean deviation below 55 HU for bone specifically
- *Voxelwise correlation coefficient*: BoneMRI accurately reconstructs the tissue radiodensity contrast, with a mean HU correlation coefficient above 0.75 for bone specifically

For Synthetic T1w images

- *Structural similarity*: The 3D image structure is accurately reconstructed with a mean structural similarity index measure (SSIM) above 0.62 in bone region
- *Peak signal-to-noise ratio*: The image voxel intensities are accurately reconstructed with a mean peak signal-to-noise ratio (PSNR) above 17.3 in bone region
- *Voxelwise correlation coefficient*: The T1-weighted image contrast is accurately reconstructed with a mean correlation coefficient above 0.78 in bone region

* *the bone region is defined as bones of interest including an approximate 7 mm area of surrounding soft tissue.*

To evaluate reduced acquisition times/accelerated MRI,quantitative voxel-by-voxel testing was performed when source MR images were acquired through accelerated scanning (i.e. scan time of 2 minutes vs. 4 minutes in the predicate device), using an k-space undersampling factor (i.e. acceleration factor) of at most 3. The objective was to validate the quantitative accuracy of BoneMRI using rigorous, objective, and unbiased statistical tests comparing bone morphology, radiodensity, and radiodensity contrast BoneMRI and CT images and in the case of accelerated source imaging, it was to confirm that BoneMRI v.2.0.0 provides accurate reconstruction quality for source MRI data for the spine region that was acquired with reduced acquisition time if the acceleration was achieved without significant SNR cost.

In each of these studies, the BoneMRI application demonstrated accurate bone morphology, radiodensity, and radiodensity contrast.

To evaluate the Synthetic T1w feature, source MR images from the spine region of patients 18 years and older were used. The performance of the Synthetic T1w feature was evaluated by assessing the correlation coefficient, the structural similarity index and peak signal to noise ratio. Based on evaluations on independent test data, it was demonstrated that the BoneMRI v.2.0.0 algorithm provides accurate synthetic T1w reconstructions in terms of T1-weighted image contrast, structure and intensity for source images of the spine region, acquired at 1.5T and 3T on Philips, Siemens and GE MRI scanners. Additionally, the BoneMRI v.2.0.0 application was successfully tested to demonstrate that Synthetic T1w images have increased T1w contrast with respect to the source data in the spine.

Furthermore a retrospective, multicenter, multireader study evaluated the diagnostic interchangeability and image quality of Synthetic T1w (sT1w) images versus conventional T1w (cT1w) images. The study dataset consisted of 59 cases (mean age 62 ± 16 years; 32 male/27 female) representing clinical pathologies including degenerative disease, trauma, infection/inflammation, oncology, and deformity.
Three independent readers (two musculoskeletal radiologists, one neuroradiologist) evaluated the images across three blinded sessions, with a one-month washout period between diagnostic assessments. The primary endpoint assessed diagnostic interchangeability using a non-inferiority threshold of -10%. Study results confirmed diagnostic interchangeability, with differences for all high-level pathology categories ranging between -1.1% and +0.6% and the 95% confidence interval remaining above the -10% threshold.
Regarding image quality, a side-by-side comparison using a 5-point Likert scale indicated that Synthetic T1w images were equal to or better than conventional T1w images, with 93% of scores being 3 or higher and a mean score of 3.3. These findings demonstrate that synthetic T1w images generated via the BoneMRI application are diagnostically interchangeable with conventional T1w images and provide high image quality, supporting their utility in clinical practice for patients indicated for spinal BoneMRI.

Thus, the BoneMRI device, providing BoneMRI and Synthetic T1w images, is a useful tool to qualitatively and quantitatively assess the bony anatomy of the pelvic region and spine.

10. Substantial Equivalence Conclusion

The subject BoneMRI application has the same intended use and a similar indication as the identified predicate device, its predecessor (BoneMRI, K233030). The technological features of the BoneMRI application are the same as the identified predicate device. Therefore, we conclude that the BoneMRI application is substantially equivalent to the identified predicate device.