February 16, 2023

Shanghai United Imaging Intelligence Co., Ltd.
% Xin GAO
Regulatory Affairs Specialist
No. 2258 Chengbei Road, Jiading District
Shanghai, Shanghai 201807
CHINA

Re: K222755
Trade/Device Name: uMR 680
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: January 11, 2023
Received: January 17, 2023

Dear Xin GAO:

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
OHT8: 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)*
K222755

Device Name
uMR 680

Indications for Use *(Describe)*
The uMR 680 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.

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 K222755

1. **Date Prepared [21 CFR 807.92(a)(1)]**
   February 15, 2023

2. **General Information [21 CFR 807.92(a)(1)]**

Manufacturer: Shanghai United Imaging Healthcare Co., Ltd
2258 Chengbei Rd., Jiading District, Shanghai, 201807

Contact Person: Xin GAO
Regulatory Affairs Specialist
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3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	uMR 680
Common Name:	Magnetic Resonance Diagnostic Device
Model:	uMR 680
Product Code:	LNH
Regulation Number:	892.1000
Device Class:	II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

The identification of predicates device within this submission is as follow:

Predicate Device
Manufacturer: Shanghai United Imaging Healthcare Co., Ltd
Device Name: Magnetic Resonance Diagnostic Device
Product Code: LNH
Device Class: II
Regulation Number: 21 CFR 892.1000
FDA 510 (k) #: K201540

5. **Device Description [21 CFR 807.92(a)(4)]**

The uMR 680 is a 1.5T superconducting magnetic resonance diagnostic device with a 70cm size patient bore. It consists of components such as magnet, RF power amplifier, RF coils, gradient power amplifier, gradient coils, patient table,

spectrometer, computer, equipment cabinets, power distribution system, internal communication system, and vital signal module etc. The uMR 680 Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

6. Intended Use [21 CFR 807.92(a)(5)]

The uMR 680 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional imag es, and spectroscopic images, and that display internal anatomical structure and/or fu nction of the head, body and extremities.

These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agen ts may be used depending on the region of interest of the scan.

7. Technological Characteristic [21 CFR 807.92(a)(6)]

The differences from the predicate device are discussed in the comparison table in this submission as below.

Table 1 Comparison of Hardware configuration

ITEM	This submission uMR 680	Predicate Device uMR 570	Remark
General			
Product Code	LNH	LNH	Same
Regulation No.	21 CFR 892.1000	21 CFR 892.1000	Same
Class	II	II	Same
Indications For Use	The uMR 680 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.	The uMR 570 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities. These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist the diagnosis. Contrast agents may be used depending on the region of interest of the scan.	Same
Magnet system			
Field Strength	1.5 Tesla	1.5 Tesla	Same

ITEM	This submission uMR 680	Predicate Device uMR 570	Remark
Type of Magnet	Superconducting	Superconducting	Same
Patient-accessible bore dimensions	70cm	70cm	Same
Type of Shielding	Actively shielded, OIS technology	Actively shielded, OIS technology	Same
Magnet Homogeneity	1.40ppm @ 50cm DSV 0.90ppm @ 45cm DSV 0.45ppm @ 40cm DSV 0.190ppm @ 30cm DSV 0.120ppm @ 20cm DSV 0.040ppm @ 10cm DSV	1.40ppm @ 50cm DSV 0.90ppm @ 45cm DSV 0.72ppm @ 40cm DSV 0.420ppm @ 30cm DSV 0.240ppm @ 20cm DSV 0.040ppm @ 10cm DSV	Note 1
Gradient system			
Max gradient amplitude	45mT/m	45mT/m	Same
Max slew rate	200T/m/s	200T/m/s	Same
Shielding	active	active	Same
Cooling	water	water	Same
RF system			
Resonant frequencies	63.87 MHz	63.87 MHz	Same
Number of transmit channels	1	1	Same
Number of receive channels	Up to 96	Up to 48	Note 2
Amplifier peak power per channel	18 kW	20 kW	Note 3
RF Coils			
Head & Neck Coil -16	No	Yes	Note 4
Head & Neck Coil -24	Yes	No	Note 5
Spine Coil - 24	No	Yes	Note 6
Spine Coil - 32	Yes	No	Note 7
Body Array Coil - 6	No	Yes	Note 8
Body Array Coil - 12	Yes	Yes	Same
Body Array Coil - 24	Yes	No	Note 8

ITEM	This submission uMR 680	Predicate Device uMR 570	Remark
Breast Coil - 10	Yes	Yes	Same
Knee Coil - 12	Yes	Yes	Same
Lower Extremity Coil - 24	Yes	Yes	Same
Shoulder Coil - 12	Yes	Yes	Same
Small Loop Coil	Yes	Yes	Same
Wrist Coil - 12	Yes	Yes	Same
Cardiac Coil - 24	Yes	Yes	Same
Foot & Ankle Coil - 24	Yes	Yes	Same
Temporomandibular Joint Coil - 4	Yes	Yes	Same
Head Coil - 24	No	Yes	Note 9
Head Coil - 12	No	Yes	Note 9
Carotid Coil - 8	Yes	Yes	Same
Flex Coil Large - 4	No	Yes	Note 10
Flex Coil Large - 8	Yes	No	Note 10
Flex Coil Small - 4	No	Yes	Note 11
Flex Coil Small - 8	Yes	No	Note 11
Infant Coil-24	Yes	No	Note 12
SuperFlex Large - 12	Yes	No	Note 13
SuperFlex Small - 12	Yes	No	Note 14
SuperFlex Body - 24	Yes	No	Note 15
Patient table			
Maximum supported patient weight	Patient Table: 250 kg	Patient Table: 250 kg	Same
	Dockable Patient Table: 310kg	No	Note 16
Accessories			

ITEM	This submission uMR 680	Predicate Device uMR 570	Remark
Vital Signal Gating	Support ECG/Respiratory/Pulse signal triggering the scan	Support ECG/Respiratory/Pulse signal triggering the scan	Same

Note 1	The homogeneity of the magnet is equal or better at typical DSVs thus the clinical scanning of the proposed device is not limited compared to the predicate device.
Note 2	More receive channels allow the proposed device to use new high-channel count and bigger coverage receive coils.
Note 3	The RF Amplifier power is just one of the influence factors to affect the B1 field, other influence factors such as efficiency of transmitting coil, damping of transmitting chain, the distance between coil and target location will also affect the intensity of B1 field, and the intensity of B1 field can be adjusted by different sequences. Generally the target B1 field is achieved by system calibration procedures and the required RF power is always less than the maximum RF Amplifier power output, so this difference from predicate device will not affect the system effectiveness, and the system safety is explained in device description and verified by the third party safety report.
Note 4	Compared to the predicate device, the proposed device removes Head & Neck Coil -16 but adds Head & Neck Coil -24. The intended use of Head & Neck Coil -24 is equivalent to previously cleared Head & Neck Coil -16. More coil elements in the new coil allow larger coverage for bigger patient.
Note 5	The intended use of Head & Neck Coil -24 is equivalent to previously cleared Head & Neck Coil -16. More coil elements in the new coil allow larger coverage for bigger patient.
Note 6	Compared to the predicate device, the proposed device removes Spine Coil - 24 but adds Spine Coil - 32. The intended use of Spine Coil - 32 is equivalent to previously cleared Spine Coil - 24. More coil elements in the new coil allow larger coverage for bigger patient.
Note 7	The intended use of Spine Coil - 32 is equivalent to previously cleared Spine Coil - 24. More coil elements in the new coil allow larger coverage for bigger patient.
Note 8	Compared to the predicate device, the proposed device removes Body Array Coil-6 but adds Body Array Coil-24. The intended use of Body Array Coil-24 is equivalent to previously cleared Body Array Coil-6. More coil elements in the new coil allow larger coverage for bigger patient.
Note 9	Compared to the predicate device, the proposed device removes Head Coil – 12 and Head Coil – 24. The intended use of Head Coil can be overridden by Head & Neck Coil -24, so this difference from predicate device will not affect the system effectiveness.
Note 10	Compared to the predicate device, the proposed device removes Flex Coil Large - 4 but adds Flex Coil Large - 8. The intended use of Flex Coil Large - 8 is equivalent to previously cleared Flex Coil Large - 4. More coil elements in the new coil allow larger coverage for bigger patient.
Note 11	Compared to the predicate device, the proposed device removes Flex Coil Small - 4 but adds Flex Coil Small - 8. The intended use of Flex Coil Small - 8 is equivalent to previously cleared Flex Coil Small - 4. More coil elements in the new coil allow larger coverage for bigger patient.
Note 12	The proposed device adds Infant Coil-24 to facilitate the exam of infant.
Note 13	The intended use of SuperFlex Large - 12 is essentially identical to previously cleared Flex Coil Large - 8. The differences are the number of channels of the coil

	and the material used on the surface of the coil. More coil elements in the new coil can better cover the scanning parts and the flexible material is beneficial to wrap the scanning parts.
Note 14	The intended use of SuperFlex Small - 12 is essentially identical to previously cleared Flex Coil Small - 8. The differences are the number of channels of the coil and the material used on the surface of the coil. More coil elements in the new coil can better cover the scanning parts and the flexible material is beneficial to wrap the scanning parts.
Note 15	The intended use of SuperFlex Body - 24 is essentially identical to previously cleared Body Array Coil - 12. The differences are the number of channels of the coil and the material used on the surface of the coil. More coil elements in the new coil can better cover the scanning parts and the flexible material is beneficial to wrap the scanning parts.
Note 16	The proposed device adds Dockable Patient Table to facilitate patient transfer and have a higher load capacity.

Table 2 provides the new application software features of the proposed device in comparison to the predicate device.

Table 2 Comparison of the new Application Software Features

ITEM	**This submission uMR 680**	**Predicate Device uMR 570**	**Remark**
Imaging Features			
Non-uniformity Correction	Yes	Yes	Non-uniformity correction is used for correcting image intensity non-uniformity caused by transmit field or receive field.
Distortion Correction	Yes	Yes	Distortion correction is used for correcting the distortion caused by the non-linear gradient field in image domain.
Image Filter	Yes	Yes	Image filter is used for denoising, enhancement and edge smoothness.
WFI	Yes	Yes	WFI is short for water fat imaging and separates water and fat signal according to chemical shift effect.
SWI	Yes	Yes	Susceptibility Weighted Imaging (SWI) uses high-pass filter to generate local phase map, then it is multiplied onto the magnitude data to generate SWI image.
PC	Yes	Yes	PC combines two images with flow encoding and without flow encoding to achieve angiography imaging.
GETI	Yes	Yes	GETI is short for gradient echo train imaging. It combines multi-echo images by sum-of-square to generate hybrid T2* contrast.
ADC	Yes	Yes	Apparent diffusion coefficient (ADC) fits logarithm-linear least squares model to represent water molecular diffusion motion by DWI technique.

FACT	Yes	Yes	FACT is short for fat analysis and calculation technique and substantially equivalent to WFI. It not only separates water and fat signal and quantifies fat fraction and R2* mapping according to chemical shift effect and T2* effect.
PSIR	Yes	Yes	PSIR is substantially equivalent to FFT reconstruction and acquire real image from two TI(time-inversion) images which is benefit for more stable contrast.
cDWI	Yes	Yes	cDWI is substantially equivalent to DWI and generates fitting b-value from multiple acquisition b values.
Inline T1/T2* Map	Yes	Yes	Inline T1/T2* Map is substantially equivalent to T1/T2* Map processed by post-processing module. The map result displays inline without extra operation by post-processing module.
Inline T2 Map	Yes	No	Inline T2 Map is substantially equivalent to T2 Map processed by post-processing module. The map result displays inline without extra operation by post-processing module.
SWI+	Yes	Yes	SWI+ is substantially equivalent to SWI and acquires multi-echo to achieve more information than SWI.
Arterial Spin Labeling (ASL)	Yes	Yes	ASL is substantially equivalent to FSE and uses extra arterial spin labeling preparation and imaging processing for cerebral blood flow (CBF) imaging without contrast agent.
Flow Quantification (FQ)	Yes	No	FQ is substantially equivalent to GRE and uses extra flow encoding and imaging processing for flow quantification.
Cardiac T1 Mapping	Yes	No	Cardiac T1 mapping is substantially equivalent to GRE and uses multiple TI acquisitions with IR preparation and imaging processing for cardiac T1 mapping.
Cardiac T2 Mapping	Yes	No	Cardiac T2 mapping is substantially equivalent to GRE and uses multiple T2-prep duration preparation acquisitions and imaging processing for cardiac T2 mapping.
Cardiac T2* Mapping	Yes	No	Cardiac T2* mapping is substantially equivalent to GRE and uses multiple TE acquisitions and imaging processing for cardiac T2* mapping.
DeepRecon	Yes	No	DeepRecon is a deep-learning based image processing algorithm for image

			de-noising and K-space-interpolation based image super-resolution.
QScan	Yes	No	QScan is short for quiet scan. It doesn't change the sequence mechanism and only optimizes gradient waveform to reduce MR scan acoustic noise.
Workflow Features			
EasyScan	Yes	No	EasyScan feature allows automatic slice positioning for Head, cardiac, c-spine, t-spine, l-spine, shoulder, abdomen and knee imaging. The positioning can also be adjusted manually by user. The final positioning effect is equivalent to manual operation without EasyScan feature.
Function			
Remote Assistance	Yes	No	Remote Assistance intends for remote support and service.
MR conditional implant mode	Yes	No	In MR conditional implant mode，user can set the safety conditions of the MR conditional implant, and uMR 680 system ensure the scanning complies with the conditions.
Spectroscopy Sequences			
Liver Spectroscopy	Yes	No	Liver spectroscopy is substantially equivalent to Spectroscopy and uses multi-echo acquisition and post-processing instead of single echo for fat quantification of liver.
Prostate Spectroscopy	Yes	No	Prostate spectroscopy is substantially equivalent to Spectroscopy and uses characteristic metabolites detection post processing for prostate spectroscopy.
Breast Spectroscopy	Yes	No	Breast spectroscopy is substantially equivalent to Spectroscopy and uses characteristic metabolites detection post processing for breast spectroscopy.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Summary of Non-Clinical Tests:

The following testing was conducted on the uMR 680 Magnetic Resonance Diagnostic Device as the predicate device:

- ES60601-1:2005/(R)2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- 60601-2-33 Ed. 3.2:2015 Medical Electrical Equipment - Part 2-33: Particular

Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic

- IEC 60825-1 Edition 2.0 2007-03, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- IEC 62464-1 Edition 2.0: 2018-12, Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.
- MS 1-2008(R2020), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 2-2008(R2020), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- MS 3-2008(R2020), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- MS 5-2018, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- MS 6-2008(R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- MS 8-2016, Characterization Of The Specific Absorption Rate For Magnetic Resonance Imaging Systems
- MS 9-2008(R2020), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

Summary of Clinical Tests:

- Sample clinical images were provided to support the ability of uMR 680 to generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

Summary of the Machine Learning Algorithm (DeepRecon):

DeepRecon is a deep-learning based image processing algorithm for image de-noising and K-space-interpolation based image super-resolution.

The training data of DeepRecon were collected from 264 volunteers. Each subject was scanned by UIH MRI systems for multiple body parts and clinical protocols, resulted in a total of 165,837 cases. In terms of the ground truth and input images in training dataset, the multiple-averaged images with high-resolution and high SNR were collected as the ground-truth images. The input images were generated from the

ground-truth images by sequentially reducing the SNR and resolution of the ground-truth images. All data were manually quality controlled before included for training.

The DeepRecon has undergone performance testing on 68 US subjects with diverse demographic distributions covering various genders, age groups, ethnicities, and BMI groups (Table a).

Table a. DeepRecon American Volunteers' Demographic Distribution

Subjects' Characteristics	**Total(N=68)**
Gender	
Male	24
Female	44
Age	
18-29	11
30-44	14
45-64	24
>=65	19
Ethnicity	
White	26
Black	17
Asian	19
Hispanic (of any race)	6
Body Mass Index (BMI)	
Underweight (<18.5)	2
Healthy weight (18.5-24.9)	17
Overweight (25.0-29.9)	25
Class1 Obesity (30.0-34.9)	14
Class2 Obesity (35-39.9)	5
Class3 Obesity (>=40)	5

The independence of testing datasets were ensured by collecting testing data from various clinical sites and during separated time periods and on subjects different from the training data. Thus, the testing data have no overlap with the training data and are completely independent. The acceptance criteria for performance testing and the corresponding testing results can be found in Table b**.**

Table b. The performance evaluation report criteria of DeepRecon

Evaluation Item	Acceptance Criteria	Test Result	Results
Image SNR	DeepRecon images achieve higher SNR compared to the images without DeepRecon (NADR)	NADR: 137.03 DeepRecon: 186.87	PASS
Image Uniformity	Uniformity difference between DeepRecon images and NADR images under 5%	0.03%	PASS
Image Resolution	DeepRecon images achieve 10% or higher resolution compared to the NADR images	15.57%	PASS
Image Contrast	Intensity difference between DeepRecon images and NADR images under 5%	1.0%	PASS
Structure Measurement	Measurements on NADR and DeepRecon images of same structures, measurement difference under 5%	0%	PASS

The DeepRecon has been validated to provide image de-nosing and super-resolution processing using various ethnicities, age groups, BMIs, and pathological variations. In addition, DeepRecon images were evaluated by American Board of Radiologists certificated physicians, covering a range of protocols and body parts. The evaluation reports from radiologists verified that DeepRecon meets the requirements of clinical diagnosis. All DeepRecon images were rated with equivalent or higher scores in terms of diagnosis quality.

The test results demonstrated that the device performs as expected and thus, it is substantially equivalent to the predicate devices to which it has been compared.

9. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, we concludes that uMR 680 Magnetic Resonance Diagnostic Device is substantially equivalent to the predicate device. It does not introduce new indications for use, and has the same technological characteristics and does not introduce new potential hazards or safety risks.