1. **Date Prepared [21 CFR 807.92(a)(1)]**
   November 12, 2018

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

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3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

**Trade Name:** uMR 580, uMR 588
**Common Name:** Magnetic Resonance Diagnostic Device
**Model:** uMR 580, uMR 588
**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:** uMR 560
**Product Code:** LNH
**Device Class:** II
**Regulation Number:** 21 CFR 892.1000
**FDA 510 (k) #:** K180926

**Reference Device**
**Manufacturer:** Shanghai United Imaging Healthcare Co., Ltd
**Device Name:** uMR 570

**Product Code:** LNH
**Device Class:** II
**Regulation Number:** 21 CFR 892.1000
**FDA 510 (k) #:** K180925

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

The uMR 580/uMR 588 is a 1.5T superconducting magnetic resonance diagnostic device with a 60cm 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 580/uMR 588 Magnetic Resonance Diagnostic Device is designed to conform to NEMA and DICOM standards.

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

The uMR 580/uMR 588 system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, 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.

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

The uMR 580/uMR 588 has the same major technological characteristics as the predicate device. The difference from the predicate device is gradient performance which is discussed in the comparison table in this submission. The same scientific technology theory, similar physical design, same coil applications and functionalities are applied to both the uMR 580/uMR 588 and predicate device. The technical characteristic differences do not affect the safety and effectiveness of the uMR 580/uMR 588 for intended use.

## 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 580/uMR 588 Magnetic Resonance Diagnostic Device as the predicate device:

- ES 60601-1:2005/(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. 3.1:2013, 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
- MS 1-2008(R2014), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 2-2008(R2014), Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- MS 3-2008(R2014), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 4-2010, Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices
- MS 5-2010, 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 8-2008, Characterization Of The Specific Absorption Rate For Magnetic Resonance Imaging Systems
- MS 9-2008(R2014), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images

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.

**Summary of Clinical Tests:**

- Sample clinical images were provided to support the ability of uMR 580/uMR 588 to generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

## 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 580/uMR 588 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.