DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 3, 2015

Alltech Medical Systems America, Inc.
% Michaeleen Dom
Manager, Quality Systems and Regulatory Affairs
28900 Fountain Parkway
SOLON OHIO 44139

Re: K141945
Trade/Device Name: Echostar Comfort 1.5T MRI System
Regulation Number: 21 CFR
Regulation Name: Magnetic Resonance Imaging System
Regulatory Class: Class II
Product Code: LNH
Dated: December 26, 2014
Received: January 6, 2015

Dear Ms. Dom:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141945

Device Name
Echostar Comfort 1.5T MRI System

Indications for Use *(Describe)*
The Echostar Comfort 1.5T MRI System is a whole-body magnetic resonance imaging (MRI) system intended for general diagnostic use. Transverse, sagittal, coronal and oblique planes may be imaged. MRI images produced by the Echostar Comfort system reflect the spatial distribution for the density of hydrogen nuclei (protons) spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images yield information that can be useful in the determining of a diagnosis.

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.

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510(k) Summary

In accordance with 21 CFR 807.92, the following summary is provided:

21 CFR 807.92 (a)(1) Submitter

Alltech Medical Systems America, Inc.
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Solon, OH 44139
Phone: (440) 424-2240
Fax: (440) 424-2255
Contact: Michaeleen Dom
Date Prepared: December 19, 2014

21 CFR 807.92 (a)(2) Name of the Device

Trade Name: Echostar Comfort 1.5T MRI System
Common Name: Magnetic Resonance Imaging System
Classification Name: Magnetic Resonance Diagnostic Device (21 CFR 892.1000, Product Code LNH)

21 CFR 807.92 (a)(3) Legally Marketed Device

Alltech Medical Systems America, Inc. is claiming substantial equivalence to a device that has been found to be substantially equivalent through the 510(k) premarket notification process, the Echostar Spica 1.5T MR System. The Echostar Spica 1.5T MR system was cleared by the FDA on May 2, 2012 (K113511).

21 CFR 807.92 (a)(4) Device Description

The Echostar Comfort 1.5T MRI System represents a modification to the previously cleared Echostar Spica 1.5T MR system (K113511); both utilize a superconducting magnet, gradients, RF transmission, various sequences and reconstruction algorithms to acquire 2D single slice, multi-slice and 3D volume images. The data acquisition system supports multiple coil elements including a body coil, head coil, spine coil, c-spine (neck) coil, shoulder coil, knee coil, small-4 element torso coil, large-12 element torso coil, wrist coil, medium-8 element torso coil, small flex coil and large flex coil.

21 CFR 807.92 (a)(5) Intended Use

The Echostar Comfort 1.5T MRI System and Echostar Spica 1.5T MR system are indicated for use as a whole body magnetic resonance diagnostic device (MRDD) that uses transverse, sagittal, coronal and oblique planes to image internal structures or functions of the body including head and extremities. MRI images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic

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resonance (NMR). The NMR properties of body tissues and fluids are hydrogen density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow dynamics. These images, when interpreted by a trained physician, yield information that can be useful in diagnosis.

21 CFR 807.92 (a) (6) Comparison with Predicate Device

The changes to the device, Echostar Comfort 1.5T MRI System reflected in this 510(k) submission do not alter the fundamental scientific technology of the Echostar Spica 1.5T MR system that was cleared by the FDA through K113511. The Echostar Comfort 1.5T MRI System has the same classification information, the same intended use, the same indications for use, the same design principles, similar product design and specifications, the same performance of effectiveness and safety as the predicate Echostar Spica 1.5T MR system. The main modifications include additional RF coils, modifications to the magnet to accommodate a 70+ cm clear bore opening, RF transmit components specified to provide RF transmit performance required for all specified sequences, gradient subsystem specified to provide higher gradient strength and slew rate. The Echostar Comfort 1.5T MRI System includes the same software sequences and applications modified for scan performance improvements.

21 CFR 807.92 (b) (1) and (2) Performance Testing - Summary of Test Data

Safety and performance nonclinical testing were conducted to the appropriate standards on the filing device, Echostar Comfort 1.5T MRI System, that were used in the testing of the Echostar Spica 1.5T MR system, to verify and validate its substantial equivalence. Sample phantom and clinical images, and test reports are presented for the changes, demonstrating conformance with the standard and equivalent performance with the predicate device. Testing was conducted as applicable to the following standards:

- AAMI ANSI ES 60601-1:2005/(R)2012
- IEC 60601-1-2:2007
- IEC 60601-2-33:2010
- NEMA MS-1 2008
- NEMA MS-2 2008
- NEMA MS-3 2008
- NEMA MS-4 2010
- NEMA MS-5 2010
- NEMA MS-6 2008
- NEMA MS-8 2008

21 CFR 807.92 (b) (3)Conclusion

Based on the results of the safety and performance testing, it is the opinion of Alltech Medical Systems America, Inc. that the device, Echostar Comfort 1.5T MRI System, is substantially equivalent to the Echostar Spica 1.5T MR System predicate device. The Echostar Comfort 1.5T MRI System has the same technological characteristics of the predicate device, does not include any new indications for use and no new or additional safety concerns have been raised.