alltech
Alltech Medical Systems America
6551 Cochran Road Solon, OH 44139
Tel:1-440-424-2240 Fax:1-440-424-2255

K113511

MAY - 2 2012

510(k) Summary

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

(1) Submitter

Alltech Medical Systems America, Inc.
6551 Cochran Road
Solon, OH 44139
Phone: 440-424-2240
Contact: Michaeleen (Micki) Dom
Date Prepared: November 23, 2011

(2) Name of the Device

Trade Name: Echostar Spica 1.5 T MR System
Common name: Magnetic resonance imaging scanner
Classification name: Magnetic resonance diagnostic device (21 CFR 892.1000, Product Code LNH & MOS)

(3) 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 Alltech EchoStar 1.5 T. The Alltech EchoStar 1.5 T. was cleared by the FDA on August 06, 2008 (K082100).

(4) Device Description

The Echostar Spica 1.5 T MR System represents a modification to the previously cleared Echostar 1.5 T (K082100); 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 and wrist coil.

(5) Intended Use

The Echostar 1.5T and Echostar Spica 1.5 T MR Systems 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 resonance (NMR). The NMR properties of body tissues and fluid 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. The device is intended for prescription use only.

(6a) Comparison with Predicate Device

The changes to the Echostar Spica 1.5 T MR System reflected in this 510(k) do not alter the fundamental scientific technology of the Alltech Echostar 1.5 T that was cleared by the FDA through K082100. The Echostar Spica 1.5 T MR System has the same classification information, the same intended use, the same indications for use, the same design principles, similar product design and specifications, same performance effectiveness and safety as the predicate Echostar 1.5 T. The main modifications include additional RF coils, removal of the 18kW option RF

alltech
Alltech Medical Systems America
6551 Cochran Road Solon, OH 44139
Tel:1-440-424-2240 Fax:1-440-424-2255

amplifier, optional respiratory gating, changes to the manufacturer of the magnet, changes to the software and additional sequences. These differences are slight and do not influence or raise new questions of safety and effectiveness.

(6b) Performance Testing – Summary of Test Data

Safety and performance nonclinical testing were conducted to the appropriate NEMA standards and IEC 60601-2-33 on the filing device, Echostar Spica 1.5 T MR System, that were used in the testing of Echostar 1.5 T, to verify and validate its substantial equivalence.
Sample phantom and clinical images, and test reports are presented for the changes, demonstrating conformance with the standards.

(6b) Conclusion

It is the opinion of Alltech Medical Systems America, Inc. that the Echostar Spica 1.5 T MR System is substantially equivalent to the Echostar 1.5 T MRI system predicate device. The Echostar Spica 1.5 T MR 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Michaeleen Dom
Manager, Quality Systems & Regulatory Affairs
AllTech Medical Systems America, Inc.
6551 Cochran Road
SOLON OH 44139

MAY - 2 2012

Re: K113511
Trade/Device Name: Echostar Spica 1.5TMR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 21, 2012
Received: March 23, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

alltech
Alltech Medical Systems America
6551 Cochran Road Solon, OH 44139
Tel:1-440-424-2240 Fax:1-440-424-2255

Indications for Use Form

510(k) Number (if known): K113511

Device Name:Echostar Spica 1.5TMR System

Indications for Use:

The Echostar Spica 1.5T MR 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 Spica system reflect the spatial distribution fo 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. This device is intended for prescription use only.

Prescription UseX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113511