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

April 10, 2017

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

Re: K163192
Trade/Device Name: Comfort EC710
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 10, 2017
Received: March 15, 2017

Dear Michaeleen 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.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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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)*
K163192

Device Name
Comfort EC710

Indications for Use *(Describe)*
The Comfort EC710 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 Comfort EC710 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.**

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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.
28900 Fountain Parkway Ste. A
Solon, OH 44139
Phone: (440) 424-2240
Fax: (440) 424-2255
Contact: Michaeleen Dom
Date Prepared: March 10, 2017

**21 CFR 807.92 (a)(2) Name of the Device**
Trade Name: Comfort EC710
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 Comfort 1.5T MRI System. The Echostar Comfort 1.5T MRI system was cleared by the FDA on February 3, 2015 (K141945).

**21 CFR 807.92 (a)(4) Device Description**
The Comfort EC710, a 1.5T MRI System, represents a modification to the previously cleared Echostar Comfort 1.5T MRI system (K141945); both utilize a 1.5T superconducting magnet with a 71cm bore, gradients, RF transmission, various sequences and reconstruction algorithms to acquire 2D single slice, multi-slice and 3D volume images, with a data acquisition system supporting multiple coil elements.

**21 CFR 807.92 (a)(5) Intended Use**
The Comfort EC710 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 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.

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

The changes to the device, Comfort EC710, reflected in this 510(k) submission do not alter the fundamental scientific technology of the Echostar Comfort 1.5T MRI system that was cleared by the FDA through K141945. The Comfort EC710 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 Comfort 1.5T MRI system. The Comfort EC710 software and sequences were modified for scan performance improvements and included the addition of a Field Echo- Echo Planar Imaging sequence, faster imaging methods, reduction of reconstruction time, reduction of shimming time, improved shimming accuracy, enhanced magnetic field homogeneity and image uniformity, additional imaging techniques for enhanced tissue contrast, reduction in artifacts, improved table control for better images at isocenter and improved workflow. The Comfort EC710 includes the addition of a Knee-Foot coil and 2 positioning pads.

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

Safety and performance nonclinical testing were conducted to the applicable portions of the following standards on the filing device, Comfort EC710:

- NEMA MS-1 2014
- NEMA MS-3 2014
- AAMI ANSI ES 60601-1:2005/(R)2012
- NEMA MS-4 2010
- IEC 60601-2-33:2010
- IEC 60601-1-2:2007

Software verification and validation testing were conducted and documentation provided as recommended by the FDA's Guidance for Industry and Staff: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered a "moderate" level of concern.

No clinical testing was conducted, however clinical images were obtained to confirm the performance of the knee-foot coil and the new software features.

Sample phantom and clinical images, and test data support the safety of the device. Test reports are presented for the changes, demonstrating conformance with the standard and equivalent performance with the predicate device that is

marketed for the same intended use.

**21 CFR 807.92 (b) (3) Conclusion**

The intended use, technological characteristics and performance of the Knee-Foot Coil is the same as the predicate Knee Coil.

The enhanced software features do not create a new intended use or alter the fundamental technological characteristics.

Based on the results of the safety and performance testing, it is the opinion of Alltech Medical Systems America, Inc. that the device, Comfort EC710, is substantially equivalent to the Echostar Comfort 1.5T MRI System predicate device. The Comfort EC710, a 1.5T MRI System, has the same fundamental technological characteristics of the predicate device, does not include any new indications for use and no new or additional safety concerns have been raised.