K120748

MAY - 1 2012

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510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.928(a).

Submitter Information

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Date: March 9, 2012

Trade Name: SpeedUp

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic resonance diagnostic device

Classification Number: 90LNH

Predicate Device(s)

Tradename	Common name	Class	Product code	Manufacturer	K number
G-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K111803
S-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K080968
O-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K092469
Achieva	System, nuclear magnetic resonance imaging	II	LNH	PHILIPS	K043147

Device Description

SpeedUp is a software option intended for use on G-scan, S-scan and O-scan Esaote MRI systems.

SpeedUp is an imaging technique to increase scan speed reducing the acquisition time. The sparsity which is implicit in MR images is exploited to significantly undersample the k-space, resulting in incoherent artifacts (noise like). Time is decreased reducing the number of acquired k-space lines (i.e. undersampling) and the final image can be reconstructed accurately with an appropriate non-linear reconstruction method.

Intended Use(s)

SpeedUp is an imaging technique to increase scan speed reducing the acquisition time. The sparsity which is implicit in MR images is exploited to significantly undersample the k-space, resulting in incoherent artifacts (noise like). Time is decreased reducing the number of acquired k-space lines (i.e. undersampling) and the final image can be reconstructed accurately with an appropriate non-linear reconstruction method.

Technological Characteristics

The technological characteristics of the G-scan, S-scan and O-scan systems with the addition of the SpeedUp software option, reflected in this Traditional 510(k), are substantially equivalent to those of the predicate devices.

Non-Clinical Summary

Non-clinical verification and validation testing of the G-scan, S-scan and O-scan systems, with the addition of the SpeedUp software option, was conducted according to design controls per CFR820.30. Testing demonstrated that the systems met performance requirements and are as safe and effective as the predicate devices.

Clinical Summary

Clinical images of the G-scan, S-scan and O-scan systems with the addition of the SpeedUp software option demonstrated that the systems met performance requirements and are as safe and effective as the predicate devices.

Conclusion

The G-scan, S-scan and O-scan systems with the addition of the SpeedUp software are safe and effective, and perform substantially equivalent to the legally marketed devices.

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

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MAY - 1 2012

Re: K120748
Trade/Device Name: SpeedUp
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 8, 2012
Received: March 12, 2012

Dear Ms. Scott:

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

K120748

Indications for Use Form

510(k) Number (if known): _____

Device Name: SpeedUp

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Prescription Use __X____ (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 IF 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) K120748