K122646

510(k) Summary of Safety and Effectiveness
dS Breast 16ch I/T

Submitted By: Invivo Corporation
3545 SW 47th Avenue
Gainesville, FL 32608

Date: August 29, 2012

NOV 2

Contact Person: Lisa Simpson, Regulatory Affairs Engineer
Tel: (352) 336-0010, ext. 164 Fax: (352) 336-1410

Proprietary Names: dS Breast 16ch I/T 1.5T
dS Breast 16ch I/T 3.0T

Common Name: Coil, Magnetic Resonance, Specialty

Classification Name and Reference: 21 CFR 892.1000
A magnetic resonance diagnostic device, for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance, class II.

Device Product Code and Panel Code: MOS / Radiology / 90

Device Description:
The **dS Breast 16ch I/T 1.5T and dS Breast 16ch I/T 3.0T** coils are designed for use with a Magnetic Resonance Imaging (MRI) system. The coil is designed to work in unison with the Body Coil of the MRI system, which will transmit the radio frequency (RF) signals, so that the coil may receive the resultant RF signal from the excited nuclei. The coils are designed as receive only coil for high resolution diagnostic imaging and intervention of breast. The coil provides both unilateral and bilateral images (Left, Right and Both) of the anatomy of interest and permits MR-guided biopsy and localization of lesions.

Indications for Use:
The coil is indicated for use on the order of a physician, in conjunction with Philips 1.5T and 3.0T MR scanners as an accessory to produce images of the breast, chest wall and axillary tissue, as an aid to diagnosis. The coil permits MR-guided breast biopsy and localization of lesions.

Technological Characteristics:
The fundamental scientific technology of a radio frequency (RF) coil is that the coil receives radio frequency signals from the tissue of interest.

Substantial Equivalence Information:
When compared to the predicate Breast Biopsy Coil (BBC) devices (**K032576 and K041481**), substantial equivalence of the **dS Breast 16ch (1.5 T & 3.0T)** devices is based on similarities in intended use, design features, and technological characteristics. Supporting product evaluations includes Signal-to-Noise (SNR) ratio, Image Uniformity and assessment of clinical images. Additionally, the new devices passed electrical safety testing in accordance with IEC standards.

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. Lisa Simpson
Regulatory Engineer
Invivo Corporation
3545 S.W. 47th Avenue
GAINESVILLE FL 32608

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Re: K122646
Trade/Device Name: dS Breast 16ch I/T 1.5T and dS Breast 16ch I/T 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 29, 2012
Received: August 30, 2012

Dear Ms. Simpson:

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

Enclosure

Indications for Use Form

510(k) Number (if known): K122646

Device Name: dS Breast 16ch I/T 1.5T
dS Breast 16ch I/T 3.0T

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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) K122646