OCT 4 - 2005

K052595

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

1. Device Name:	Magnetic Resonance Imaging Accessory
2. Proprietary Name:	3.0T HD Breast Array
3. Classification:	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc. 1515 Danner Drive, Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The 3.0T HD Breast Array is a receive-only RF coil, used for obtaining MR images of the breast and axillary tissue. The biopsy plates allow access to the breast anatomy during biopsy procedures. No biopsy needles are included with, or packaged with the 3.0T HD Breast Array. The indications for use are the same as for standard MR Imaging. The 3.0T HD Breast Array is designed for use with the 3.0T Signa Excite MRI scanner, manufactured by General Electric Healthcare.
8. Device Description:	The 3.0T HD Breast Array is a phased array, receive-only MRI coil. The coil consists of a main supporting base with a coil chamber in the middle section. A sternum bridge and two lateral wings divide the chamber into two segments, one to receive each breast. Each of the hollow coil segments houses four coil elements that are insulated from the patient by a rigid plastic housing. The coil housing is made of plastic materials, which are fire rated and have high impact and tensile strength. The 3.0T HD Breast Array is designed to offer optimized imaging capabilities and maximum lateral and medial access to each breast for biopsy procedures.
9. Marketed Device:	3.0T HD Breast Array
10. Comparison with Predicate:	The 3.0T HD Breast Array is a modification of the existing cleared 1.5T Liberty 9000 8-channel Breast coil (K041695), with the main difference being the coil has been retuned for operation in a 3.0T magnetic field instead of a 1.5T field strength
11. Summary of Studies:	Testing was performed to demonstrate that the design modifications to the 3.0T HD Breast Array meet predetermined acceptance criteria.

Conclusion:

It is the opinion of USA Instruments that the 3.0T HD Breast Array is substantially equivalent to the USA Instruments 1.5T Liberty 9000 8 channel Breast Array (K041695). Usage of the USA Instruments 3.0T HD Breast Array does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2005

Mr. David Brown
Manager, Quality Assurance/
Regulatory Affairs
USA Instruments
1515 Danner Drive
AURORA OH 44202

Re: K052585
Trade/Device Name: 3.0T HD Breast Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: September 16, 2005
Received: September 20, 2005

Dear Mr. Brown:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K052585

Device Name: 3.0T HD Breast Array

Indications for Use:

The 3.0T HD Breast Array is a receive-only RF coil, used for obtaining MR images of the breast and axillary tissue. The biopsy plates allow access to the breast anatomy during biopsy procedures. No biopsy needles are included with, or packaged with the 3.0T HD Breast Array. The indications for use are the same as for standard MR Imaging. The 3.0T HD Breast Array is designed for use with the 3.0T Signa Excite MRI scanner, manufactured by General Electric Healthcare.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

David G. Hyams

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052585