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SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name : Magnetic Resonance Imaging Accessory
2. Proprietary Name : Mark 5000 Phased Array Shoulder Coil
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 Mark 5000 Phased Array Shoulder is a receive-only phased array RF coil, used for obtaining diagnostic images of the shoulder and adjacent regions in Magnetic Resonance Imaging systems. The indications for use are the same as for standard MR Imaging. The Mark 5000 Phased Array Coil is designed for use with the Outlook (0.23Tesla) MRI scanner manufactured by Picker International Inc.
8. Device Description : The Mark 5000 Phased Array Coil consists of two volume RF coil elements in a quadrature design. The elements and associated circuitry are enclosed in a flexible vinyl enclosure housing. The coil is positioned on the patient's shoulder, by means of straps, during imaging.

Please Turn Over

9. Safety and Effectiveness

Parameter	Mark 5000 Phased Array Shoulder Coil	Predicate
Intended Use	Shoulder imaging applications	Phased Array Shoulder Coil Medical Advances Inc. (K945778)
Indications for Use	Identical to routine MRI imaging	Phased Array Shoulder Coil Medical Advances Inc. (K945778)
Coil Enclosure Material	Vinyl Fabric ABS/PVC plastic alloy Polyurethane Plastic	Flexible Phased Array Spine Coil Picker International (K960497) Phased Array CTL Spine Coil USA Instruments, Inc. (K980157)
Coil Design	Two channel receive-only phased array coil	Flexible Phased Array Spine Coil Picker International (K960497)
Decoupling	Switching diode decoupling	Flexible Phased Array Spine Coil Picker International (K960497)
Prevention of RF Burns	Does not transmit RF power; decoupling isolates the coil elements from RF fields during RF transmission; coil elements and circuitry are enclosed in a non-conductive housing.	Flexible Phased Array Spine Coil Picker International (K960497) Same as other Outlook Coils Picker International (K945827)
Radio Frequency Absorption	Coil is a receive only coil and does not transmit RF power; power deposition during imaging is limited by SAR algorithm	Profile 7000 Volume Neck Coil USA Instruments, Inc. (K964531) Algorithm on Outlook system (K945827)
Formation of Resonant Loop	Decoupling isolates the coil elements from RF fields during RF transmission; length of cable and stiffness does not permit looping	Profile 7000 Volume Neck Coil USA Instruments, Inc. (K964531), Flexible Phased Array Spine Coil Picker International (K960497)



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Rony Thomas
Manager, Regulatory Affairs
USA Instruments, Inc.
1515 Danner Drive
Aurora, Ohio 44202Re: K983143
Mark 5000 Phased Array Shoulder Coil
Dated: October 20, 1998
Received: October 22, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

