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SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Sharp 9000 Phased Array Brain 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 Sharp 9000 Phased Array Brain Coil is a receive-only RF coil, used for obtaining diagnostic images of the brain, brain vasculature and other intracranial structures as well as a secondary application of imaging small joints such as knees and elbows, in Magnetic Resonance Imaging Systems. The indications for use are the same as for standard MR Imaging. The Sharp 9000 Phased Array Brain Coil is designed for use with the 1.5T Signa Horizon MRI scanner manufactured by GE Medical Systems.
8. Device Description:	The Sharp 9000 Phased Array Brain Coil is a four loop receive-only coil. The coil consists of two sections: a left and right section, which are positioned on the left and right side of the patient head respectively. The left and right coil sections, each containing two loop coils and the accessory coil electronics, are enclosed in a vacuum formed housing made of polyurethane plastic, which is fire rated and has a high impact and tensile strength.

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9. Safety and Effectiveness

Sharp 9000 Phased Array Brain Coil Product Features	Comparison to predicate device or other 510(k) Cleared Products
Intended Use: Imaging of the brain, brain vasculature and other intracranial structures, as well as a secondary application of imaging small joints.	-Similar to Quadrature Brain Coil Model 340GE-21C manufactured by Medical Advances, Inc. (K982918)
Indications for Use: Identical to routine MRI imaging	-Similar to Insight 7000 Phased Array Torso Coil manufactured by USA Instruments Inc. (K972340)
Coil Enclosure Material: Polyurethane Plastic and Royalite ™ R59 ABS/PVC alloy	-Similar to Profile 7000 Quadrature Volume Neck Coil manufactured by USA Instruments, Inc. (K964531)
Coil Design: Four coil receive-only phased array design	-Similar to Insight 7000 Phased Array Torso Coil manufactured by USA Instruments, Inc. (K972340)
Decoupling: RF Chokes with Switching Diodes	-Similar to Insight 7000 Phased Array Torso Coil manufactured by USA Instruments, Inc. (K972340)
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.	-Similar to Insight 7000 Phased Array Torso Coil manufactured by USA Instruments, Inc. (K972340)
Radio Frequency Absorption: Coil is a receive only coil and does not transmit RF power; power deposition during imaging is limited by SAR algorithm	-Similar to Insight 7000 Phased Array Torso Coil manufactured by USA Instruments, Inc. (K972340)
Formation of Resonant Loops: Decoupling isolates coil elements from RF fields during RF transmission; length of cable and stiffness does not permit looping	-Similar to Insight 7000 Phased Array Torso Coil manufactured by USA Instruments, Inc. (K972340)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2000

Rony Thomas
Manager, Regulatory Affairs
USA Instruments, Inc.
1515 Danner Drive
Aurora, Ohio 44202

Re: K994042
Sharp 9000 Phased Array Brain Coil
Dated: November 22, 1999
Received: November 29, 1999
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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994042

Device Name: Sharp 9000 Phased Array Brain Coil

Indications for Use: The Sharp 9000 Phased Array Brain Coil is designed to provide Magnetic Resonance Images of the brain anatomy. The Sharp 9000 Phased Array Brain Coil is designed for use with the GE Signa Horizon 1.5T scanner.

Anatomic Regions: Brain and Head
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The Signa 1.5T system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994042

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)