K03 1731

510(k) Summary

JUL 30 2003

Summary of Safety and Effectiveness

Submitter:	SA Instruments, Inc.
Address:	65 Main Street Stony Brook, NY, 11790
Telephone:	(631) 689-0408
Contact:	President
Prepared:	May 28, 2003
Proprietary Name:	MR Fiber Optic ECG Gating System
Common/Classification Name:	Gating system
Predicate Devices:	Gating cable provided by General Electric for the 1.0 T and 1.5 T Signa MR systems

New Device Description:

The MR Fiber Optic ECG Gating System measures and digitizes the patient's electrocardiogram, detects the presence of an R-wave and provides a trigger to the Signa MR system. The gating system provides for operator control of parameters used in the R-wave detection algorithms and control of gate delay. The electrocardiogram waveform is displayed along with the gate, heart rate and the measured R to R interval.

Intended Use:

The MR Fiber Optic ECG Gating System is intended to be used when it is necessary to synchronize the MR scanner's data acquisition with the patient's electrocardiogram.

Performance Testing:

The MR Fiber Optic ECG Gating System meets IEC 601-1, IEC 601-1-2, IEC 601-2-27, IEC 801-2, -3, -4, -5, CISPR 11. In addition, tests were performed to establish that the Gating system operated in the MRI environment substantially equivalent to the predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2003

G. Ronald Morris, Ph.D.
President
SA Instruments, Inc.
P.O. Box 740
STONY BROOK NY 11790

Re: K031731
Trade/Device Name: MR Fiber Optic ECG Gating System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: May 30, 2003
Received: June 4, 2003

Dear Dr. Morris:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

INDICATIONS FOR USE

510 (k) NUMBER (IF KNOWN) K031731

DEVICE NAME: MR Fiber Optic ECG Gating System

INDICATIONS FOR USE:

The MR Fiber Optic ECG Gating System would be used when it is necessary to synchronize the MR scanner's data acquisition with the patient's electrocardiogram.

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031731

Concurrence of CDRH, Office of Device Evaluation (ODE)

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