Attachment 1

K033315

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 807.87(h)

General Information:

Trade Name:	Superopen 0.23T
Model:	NAM-P023A (MRI System)
CFR Section:	21 CFR Part 892.1000 Magnetic resonance diagnostic device
Classification Name:	System, Magnetic Resonance Imaging
Product Code:	LNH
Device Class:	Class II
Applicable Standard:	IEC60601-1, Medical electrical equipment - Part 1: General Requirements for Safety IEC60601-2-33, Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis 21 CFR Subchapter J, Radiological Health IEC60825-1, Safety of laser products-Part1:Equipment classification, requirement and user's guide DICOM 3.0 NEMA MS Series (MS1 – MS8)
Manufacture and Distributor:	NEUSOFT Digital Medical Systems Co., Ltd. No.3-11,Wenhua Road, Heping District, Shenyang, P.R.China Post Code : 110004
Submitter:	Contact : Wang Zhiqiang Title : Manager of Quality Management Department Tel : 86-24-83665003 Fax : 86-24-23782711 E-Mail : wangzq@neusoft.com
	Summary prepared : July. 16th, 2003

Safety and Effectiveness information

Intended Uses:

The Superopen 0.23T is intended to produce images that reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Device Description:

The Superopen 0.23T is a 0.23T permanent magnet MRI system. The magnet is mainly made of NdFeB material. The system software based on Windows (TM) is an interactive program with user-friendly interface. Its functions cover scanning control, image reconstruction and image/archive management and maintenance.

Predicated Device:

K030918 : Superopen 0.35T (MRI System)

Statement of Substantial Equivalence:

The Superopen 0.23T is of comparable type and substantially equivalent to the NEUSOFT Superopen 0.35T (K030918) in that they are similar in technology and intended uses. Both of these systems are open-permanent-magnet MR Imaging System, use Gradient Subsystem to provide controlled and uniform gradient magnet fields in the X, Y and Z planes, and use RF Subsystem to complete the function of RF signal transmitting/receiving and processing. Image reconstruction is controlled by console' s computer that has an interactive user interface, and the system produces 2D and 3D image that can be filmed or electronically stored for future review. Both of these systems have the traditional MRI unit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

Neusoft Digital Medical
Systems Co., Ltd.
% Mr. Heinz-Joerg Steneberg
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K033315
Trade/Device Name: Superopen 0.23T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: October 13, 2003
Received: October 15, 2003

Dear Mr. Steneberg:

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

510(k) Number (if Known) K033315

Device Name: Superopen 0.23T

Indications for use:

The Superopen 0.23T is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MRI system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.
The indications for use are as follows:

Anatomical Region:	Head, Body, Spine, Extremities
Nucleus excited:	Proton
Diagnostic uses:	T1,T2, proton density weighted imaging MR Angiography Imaging processing
Imaging capabilities:	2D, 3D Spin Echo(SE) Short time inversion recovery (STIR) Fluid attenuated inversion recovery (FLAIR) 2D,3D Field Echo (FE) 2D, 3D Field Echo with Spoiler (FESP) 2D FESP Multi-Slice (FESP-MS) 2D and 3D Field Echo Steady State FID with rephasing gradient (FESS-FID) 2D, 3D Fast Spin Echo (FSE) 2D, 3D MRCP MR Angiography 2D, 3D TOF MTC

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033315