

## Attachment 1

APR 01 2003

## Summary of Safety and Effectiveness

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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 0.35T

Model: NSM-P035 (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.  
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Shenyang, China  
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Summary prepared : Mar. 14<sup>th</sup>, 2003

**Safety and Effectiveness information**

## Intended Uses:

The Superopen 0.35T 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 0.35T is a 0.35T 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:

K974212 : AIRIS II (MRI System)  
K001334: AIRIS II Version 4.1 Software

## Statement of Substantial Equivalence:

The Superopen 0.35T is of comparable type and substantially equivalent to the Hitachi AIRIS II (K974212) and the AIRIS II Version 4.1 Software(K001334) 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.



Food and Drug Administration  
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APR 01 2003

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

Re: K030918

Trade/Device Name: Superopen 0.35T  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance  
diagnostic device

Regulatory Class: II  
Product Code: 90 LNH  
Dated: March 20, 2003  
Received: March 24, 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.

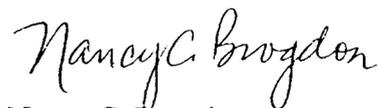
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if Known) K030918

Device Name: Superopen 0.35T

Indications for use:

The Superopen 0.35T 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  
Diffusion 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  
Echo Planar Imaging (EPI)  
Multi-shot SE / FE  
Diffusion

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Lyman*

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K030918

Prescription Use