Attachment 2 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:	CT-C3000DUAL and CT-C2800DUAL Family of Dual-slice CT Scanner Systems
Common Name:	CT Scanner
Classification Name:	21 CFR Part 892.1750 Computed Tomography X-ray System
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard UL 187, Standard for safety, X-ray Equipment IEC60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety
Manufacture:	Neusoft Digital Medical Systems Co.,Ltd No.3-11,Wenhua Road, Heping District, Shenyang, China Post Code : 110004
Distributor:	Neusoft Digital Medical Systems Co.,Ltd No.3-11,Wenhua Road, Heping District, Shenyang, China Post Code : 110004
Submitter:	*Name:* Wang Zhiqiang *Title:* Manager of Quality Management Department Who maybe contacted by telephone at 86-24-83665003 by FAX at 86-24-23782711 by E-Mail at wangzq@neusoft.com
	Summary prepared : Dec 7th, 2003

Safety and Effectiveness information

Intended Uses:

The CT-C3000DUAL and CT-C2800DUAL Family of Dual-slice CT Scanner Systems are intended to produce cross-section images of head and whole body by computer reconstruction of X-ray transmission data taken at different angles.

Device Description:

The CT-C3000DUAL and CT-C2800DUAL Family of Dual-slice CT Scanner Systems are a whole body X-ray computed tomography scanner which features a continuously rotating tube-detector system and multi-slice capability of up to 2 slices simultaneously . The system software is an interactive program used for X-ray scan control, image reconstruction, and image archive/evaluation.

Predicated Device:

CT-C3000 system (K020913)

Statement of Substantial Equivalence:

The CT-C3000DUAL and CT-C2800DUAL Family of Dual-slice CT Scanner Systems are of comparable type and substantially equivalent to the CT-C3000 system (K020913) that complies with the same or equivalent standards and has the same intended uses. Both of these system use on-board high frequency High-Voltage generator to generate X-radiation from X-ray tube. The X-ray transmission data is detected by the solid-state detector and is reconstructed by the computer which has an interactive user interface. Both of these devices produce two dimensional image and 3D image that can be filmed or electronically stored for future review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Neusoft Digital Medical
Systems Co., Ltd.
% Mr. Tamas Borsai
510(k) Third Party Review Program Manager
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K041542
Trade/Device Name: CT-C3000DUAL and CT-C2800DUA
Family of Dual-slice CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: June 2, 2004
Received: June 8, 2004

Dear Mr. Borsai:

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 such 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

Attachment 3 Indications for Use

510(k) Number (if known): K041542

Device Name: CT-C3000DUAL and CT-C2800DUAL Family of Dual-slice CT Scanner Systems

Indications for Use:

The CT-C3000DUAL and CT-C2800DUAL Family of Dual-slice CT Scanner Systems are intended to produce cross-section images of head and body by computer reconstruction of X-ray transmission data taken at different angles.

David A. Lyerla
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041542

Prescription Use ✓

Concurrence of CDRH, Office of Device Evaluation (ODE)