510(K) SUMMARY

AUG - 7 2006

1.14. Identification of Submitter

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VP, New Product Development
Xoran Technologies, Inc
309 N. First Street
Ann Arbor, MI 48103
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310.525.0701 (phone)

1.15. Identification of Product

Name	xCAT™
Manufacturer:	Xoran Technologies, Inc 309 N. First Street Ann Arbor, MI 48103
Distributor	Xoran Technologies, Inc 309 N. First Street Ann Arbor, MI 48103

1.16. Marketed Devices

The xCAT™ is substantially equivalent to the devices listed below:

Device	MiniCAT™
Manufacturer	Xoran Technologies 309 N. First Avenue ~~Ann Arbor~~, MI 48103
510(k) Number	K032243
Device	NL 3000 CereTom
Manufacturer	Neurologica ~~14 Electronics~~ Ave. Danvers, MA 01923
510(k) Number	K051765

1.17. Device Description

The xCAT™ is a dedicated X-ray imaging device that acquires a 360° rotational X-ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two dimensional views of this volume. The xCAT™ can measure distances and thickness on two dimensional images. Images produced by the xCAT™ can be exported via Ethernet or onto optical media or a memory stick.

The building blocks of the xCAT™ are a motorized scanning arm carrying an X-ray source and image detector, and a computer running the xCAT™ software. The scanning arm facilitates the acquisition of a full X-ray sequence by the software. The software receives the two dimensional images acquired by the detector transforms them into three dimensional images and displays them on the computer monitor for viewing.

1.18. Intended Use

The xCAT™ is intended to be used for x-ray computed tomography imaging of anatomy that safely fits into the imaging gantry (such as the head, neck, wrist, ankle, hand, and foot).

1.19. Comparison with the Predicate Devices

The xCAT™ reconstructs a three dimensional model from X-ray images similar to those obtained using the predicate devices. It displays either two-dimensional cross-sections or three dimensional views and allows the user to take measurements on the reconstructed images. The xCAT™ is substantially equivalent in design, material, functionality, and technology to the predicate devices (Neurologica's NL 3000 CereTom, ref: K051765, and Xoran Technologies Inc. MiniCAT™ ref: K032243).

1.20. Conclusion

The xCAT™ by Xoran Technologies acquires an X-ray rotational sequence and provides three-dimensional information on the analyzed volume. It is intended to be used for x-ray computed tomography imaging of anatomy that safely fits into its imaging gantry (such as the head, neck, wrist, ankle, hand, and foot), and is substantially equivalent in design, material, functionality, and technology to Neurologica's NL 3000 CereTom, ref: K051765, and Xoran Technologies Inc. MiniCAT™ ref: K032243.

Potential hazards (e.g., electrical, mechanical, thermal, radiation, incorrect measurements, and misdiagnosis) are controlled by a risk management system including: Hazard Analysis and Software Development and Validation Process.

The xCAT™ is an X-ray imaging system that complies with the requirements of 21 CFR 807.87(h) and does not pose any new safety risks or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 7 2006

Jim Bertolina, Ph.D.
VP, New Product Development
Xoran Technologies, Inc.
309 N. First Street
ANN ARBOR MI 48103

Re: K061834
Trade/Device Name: Xoran xCat™
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 28, 2006
Received: June 29, 2006

Dear Dr. Bertolina:

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 (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 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K061834

Device Name: Xoran XCAT

Indications For Use:

The XCAT is intended to be used for x-ray computed tomography imaging of anatomy that safely fits into the imaging gantry (such as the head, neck, wrist, ankle, hand and foot).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061834