K982060

SEP 2 1998

510(k) Summary

Summary of Safety and Effectiveness

1. Device Name

Volumax CT scanner

2. Submitter

Elscint Inc.,
505 Main Str.
Hackensack, NJ 07601

3. Intended Use Of Device and its Main Features

The Volumax is used for whole body computed tomography.

The Volumax is a continuous rotation CT scanner consisting of a gantry, patient table, operator station and accessories. Its main characteristics are:

- Continuous rotation and Helix (spiral) scanning.
- Simultaneous multi-slice scanning.
- Minimum scan time of 0.3 second.
- Minimum reconstruction time of 0.5 second.

4. Predicate Devices

- CT-Twin *flash* submitted in "HRSW Option for CT-Twin Flash" K945512.
- SeleCT/SP, K961464
- OmniPro which is a trade name of ProVision, K954678

Related devices:

- XRT-7 Option for CT scanner, K964583
- Siemens Somatom Plus 4, K941546, K964747
- Siemens Magnetom Project O16, K932271

510(k) Summary

5. Safety and Effectiveness Considerations

The safety of the option is assured by adherence to GMP practices and to International Standards. Potential hazards are identified in a hazard analysis and controlled in the following manner:

Software safety is assured by the company procedures that conform to accepted practices. Quality assurance procedures were adhered to, and test results demonstrate that the option specifications and functional requirements were met.

Electrical and Mechanical safety is assured by adherence to IEC 601-1 standards.

Radiation safety is assured by compliance with 21 CFR, Subchapter J performance standards.

6. Substantial Equivalency Statement

Based on the above considerations, it is Elscint's opinion that the Volumax CT scanner scanners is substantially equivalent in safety and effectiveness to the predicate devices, CT Twin flash, K945512 and SeleCT/SP, K961464.

In our opinion it is also substantially equivalent to Siemens Somatom Plus 4, K941546, K964747.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1998

Steven M. Kay
Director, Regulatory Affairs
and Quality Assurance
Elscint, Inc.
Corporate Headquarters
505 Main Street
Hackensack, New Jersey 07601

Re: K982060
Volumax CT Imaging System
Dated: June 10, 1998
Received: June 11, 1998
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Kay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982060

Device Name: **Volumax**

Indications for Use:

Whole body computerized tomography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982060

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)