

K974344

JUN 3 1998

Summary of Safety and Effectiveness

1. Device Name

CT Scope option for CT scanners

2. Submitter

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

3. Intended Use Of Device and its Main Features

The option is used for whole body computed tomography applications and specifically for interventional procedures that are performed on the CT table.

- The CT Scope option is an addition to the CT Twin and HeliCAT families of CT scanners. It comprises of hardware and software for initiation and termination of the scan process and for on-line monitoring of the resulting images in the gantry room, in addition to the Operator Console. Exposure is initiated by one of two pedals near the patient table and terminated by releasing the pedal. Partially reconstructed images are displayed at a rate of 6 images/second with a delay of approximately one second and displayed on a monitor in the scanner room. A handle for holding the needle from outside the direct radiation to reduce the dose received by the doctor during the interventional procedure is also included.
- The optional LaserGuide may be used for marking the entrance point and angle of needle insertion externally to the gantry opening for convenience.

4. Predicate Devices

- CT-Twin *flash* submitted in "HRSW Option for CT-Twin Flash" K945512.
- HeliCAT CT scanner, K930090
- Precise Biopsy Localization by Computed Tomography, **Radiology 118**:603-607, March 1976
- Toshiba America Medical Systems Inc., Real time Reconstruction system option for Xpress/SX CT System, K950972, cleared on April 15, 1996.
- GE-YMS CT ProSpeed Family of CT Systems with ProSpeed Renaissance Options, K970606, cleared on April 4, 1997.

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5. Safety and Effectiveness

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 of the option 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.

The CT Scope option enables initiation and termination of the scan process and on-line monitoring of the resulting images in the gantry room, in addition to the Operator of the LaserGuide during the CT Scope procedure may reduce the X-ray exposure to the interventionist by enabling the initial needle insertion under LaserGuide, leaving only the final needle approach to the continuous scanning phase.

6. Substantial Equivalency Statement

Based on the above considerations, it is Elscint's opinion that scanners incorporating the CT Scope and LaserGuide options are substantially equivalent in safety and effectiveness to the predicate devices, CT Twin flash, K945512 and HeliCAT, K930090.

In our opinion they are also substantially equivalent to the interventional procedures using CT that predate the 1976 Medical Device Amendments an example of which is the article "Precise Biopsy Localization by Computed Tomography", Radiology 118:603-607, March 1976.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Steven M. Kay
Director, Regulatory Affairs
and Quality Assurance
Elscont, Inc.
Corporate Headquarters
505 Main Street
Hackensack, NJ 07601

Re: K974344
CT Scope option for CT Scanners
Dated: March 10, 1998
Received: March 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): K974344

Device Name: CT Scope option for CT Scanners.

Indications For Use:

Whole body Computed Tomography applications and specifically for interventional procedures that are performed on the CT table.

(Please do not write below this line-continue on another page if needed)

(Concurrence of CDRH, office of Device Evaluation (ODE))

Prescription Use OR Over-the-counter use
(Per 21 CFR 801.109)

David L. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974344

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