

# Summary of Safety and Effectiveness

K970980

## 1. Device Name

Cardiac Scoring option

MAY 29 1997

## 2. Submitter

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

## 3. Description of Main Features

The Cardiac Scoring option is a software option based on the Agaston scoring method for the quantification of high density structures, e.g. calcified tissues in the coronary arteries.

## 4. Predicate Devices

CT Twin *flash*, K945512,

## 5. Safety

The Level of Concern of the Cardiac Scoring was determined to be minor.

The safety of this software option is assured by the company procedures that conform to accepted practices. The key process stages are:

- Definition of Requirements
- Design
- Implementation
- Verification and Validation

Good quality assurance procedures were adhered to, and test results demonstrate that the option specifications and functional requirements were met.

## 6. Effectiveness

The Cardiac Scoring option quantifies calcifications by a weighted number instead of manual calculation of area x density products. As such it is easier to use.

## 7. Substantial Equivalency Statement

Based on the above considerations, it is Elscint's opinion that the Cardiac Scoring option is substantially equivalent in safety and effectiveness to the Histogram and ROI functions of the predicate device, CT Twin *flash*, K945512.



MAY 29 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Thomas J. Spackman, M.D., F.A.C.R.  
President and Chief Executive Officer  
Elscent, Inc.  
86 Orchard Street  
Hackensack, NJ 07601Re: K970980  
Cardiac Scoring for CT Scanners  
Dated: March 11, 1997  
Received: March 18, 1997  
Regulatory Class: II  
21 CFR 892.1750/Procode: 90 JAK

Dear Dr. Spackman:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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/dsmmain.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): K970980

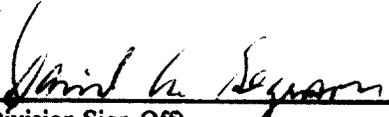
Device Name: Cardiac Scoring for CT Scanners

Indications For Use: Cardiac scoring from whole body computed tomography derived measurements

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

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K970980

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_