Scandia Corporation
10200 Dennis Drive, Suite 5
Urbandale, Iowa 50322
Phone: 515-334-5131

K101391

SECTION G
510(K) SUMMARY

In accordance with 21CFR 807.92

1.0 Submitter Information

AUG 0 4 2010

Name: Scandia Corporation

Address: 10200 Dennis Drive, Suite 5
Urbandale, Iowa 50322

Phone: 515-334-5131
Fax: 515-334-5145

Contact Person: David Askew, Chief Operations Officer

Date of Submission: April 16, 2010

2.0 Device Identification

Name of Device: Scandia-45

Common Name: Scintillation (Gamma) Camera System

Classification Name: Emission Computed Tomography System

3.0 Identification of Equivalent Device

1. *T-Quest* - MEDX Corporation – **[K073456]**

4.0 Description of Device

The Scandia-45 is a high resolution, SFOV digital gamma camera for thyroid and small organs imaging. The Scandia-45, is made up of a single, small-field detector assembled with high optical and mechanical quality. The systems has 45 high quantum efficiency photomultipliers characterized by improved energy resolution, magnetic shielding and long-term stability and utilizes a compact, highly integrated, one board, easily serviceable construction without tuning potentiometers. The acquisition console has full-digital electronics, including fast PCI bus acquisition interface. The system also has a light-weight, easily-adjustable gantry and light, easily-exchangeable microcast collimators.

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5.0 Intended Use / Indications for Use

For use in the acquisition, processing, display, and analysis of planar images of the thyroid and other small organs.

6.0 Technological Characteristics

The Scandia-45 Gamma Camera System is a small, mobile scintillation camera with a gantry, a single small-field detector, an acquisition station, and related hardware and software components. The characteristics of the Scandia-45 compare substantially with the predicate device in materials used, technology applied, and functional methodology.

Thus, the Scandia-45 Gamma Camera System raises no new issues of safety or efficacy.

7.0 Performance Testing and Data

Performance testing was performed using NEMA NU1 phantoms, under the NEMA Standard test protocols. In all cases, performance of the Scandia-45 device met or exceeded that of predicate device.

Clinical images were obtained using the Scandia-45 in human subjects. Image quality was at least equal to images produced by reference predicate devices.

Furthermore, electrical safety testing has been performed and found to meet applicable standards and defined acceptance criteria.

8.0 Substantial Equivalence

The Scandia-45 Gamma Camera System has the same intended use, similar principles of operation, and consistent technological characteristics as the predicate devices. Thus, the Scandia-45 is substantially equivalent to the predicate devices and no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. David Askew
Chief Operations Officer
Scandia Corporation
10200 Dennis Drive, Suite 5
URBANDALE IA 50322

AUG 04 2010

Re: K101391
Trade/Device Name: Scandia-45
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: II
Product Code: IYX
Dated: May 1, 2010
Received: May 18, 2010

Dear Mr. Askew:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101391

Device Name: Scandia-45

AUG 04 2010

Indications for Use:

The Scandia-45 is indicated for use in the acquisition, processing, display, and analysis of planar images of the thyroid and other small organs

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101391