K011763

SEP - 5 2001

510(k) Summary

This summery is submitted in compliance with 21 CFR 807.92

(a) (1) Submitted by: Scanditronix Medical AB
Stålgatan 14,
S-754 50 Uppsala
Sweden

Trade name of the company: Scanditronix Wellhöfer

Contact persons: Sten Larsson
or
Alf Öhman
+46 18 18 07 00

Date of preparation: 31 May -2001

(2) Trade name of device: OmniDos

Common name: General Dosimetry System

Classification name: (Accessory to) Radionuclide radiation therapy system, §892,5750; X-ray radiation therapy system, §892,5900; and Medical charged-particle radiation therapy system, §892.5050.

(3) Identification of predicate marketed device:

WP700 (Wellhöfer Dosimetrie) FDA K945321/S1, 1995, 29th of March.
RFA-300 (Scanditronix Medical) FDA K934303/S1, 510(k) Aug 1994,
RFA-300, LDA Utility (Scanditronix Medical) FDA K961400: Jan. 1997

(4) Description of the device:

The Scanditronix & Wellhöfer OmniDos is a General Dosimetry System similar to
Wellhöfer Dosimetrie: WP700, FDA K945321/S1, 1995, 29th of March.
Scanditronix Medical: RFA-300, FDA K934303/S1, 510(k) Aug 1994,
Scanditronix Medical: RFA-300, LDA Utility, FDA K961400: Jan. 1997.

OmniDos and the marketed predicated products are radiotherapy quality assurance measuring devices designed to measure dose distribution.

Using appropriate detectors and servo/scanners, the dose distribution can be accurately measured to provide acceptance testing, beam tuning, routine beam verifications, isodose tracking and linear scans.
These devices are designed to function in conjunction with a PC, which controls the relative position of the detectors while measuring and storing dose information of the radiotherapy beam. Each device is designed to provide two or more channels from electrometers which have their results converted into digital information for storage, display, or transfer to other systems for radiation therapy treatment planning using data formats suitable for the other system.
Depending on configuration the devices offer several options for use of the detector system, including film scanning, TMR measurements, and other options.

(5) Intended use:

OmniDos is a system software utilising hardware components to measure radiation dose distribution. The hardware consists of water phantoms, air scanners, film scanners/ digitizers and single or array detectors. The hardware comes from Scanditronix Medical, the sister company Wellhöfer Dosimetry and from 3'd party vendors.
OmniDos is used to accurately analyse and handle the measured dose distribution in quality assurance purposes, for calibration of radiation devices, as input data to Treatment Planning Systems, for acceptance testing, beam tuning and in research.

(6) Technological comparison:

The Scanditronix Medical AB OmniDos is a General Dosimetry System similar to
Wellhöfer Dosimetrie: WP700, FDA K945321/S1, 1995, 29th of March.
Scanditronix Medical: RFA-300, FDA K934303/S1, 510(k) Aug 1994,
Scanditronix Medical: RFA-300, LDA Utility, FDA K961400: Jan. 1997.

(b) (1) Non-Clinical tests:

The OmniDos system consists of the OmniDos software and hardware. The hardware consists of the same devices as the hardware of the above systems (WP700, RFA-300, RFA-300 with LDA Utility). The final tests have been performed for the whole system consisting of software and hardware.

Comparison of operational characteristics for the Scanditronix Medical OmniDos General Dosimetry System and the predicate product show similar results that are suitable for their intended purpose. To minimize potential electrical hazards, Scanditronix Medical and its sister company Wellhöfer Dosimetrie GmbH adheres to recognized and established industry practice, and all devices are subject to final performance testing. The Scanditronix Medical OmniDos General

Dosimetry System is designed for conformance with IEC 601-1 standards for electrical isolation and leakage current and meets electrical performance standards for CSA and UL.
The electrometers of Scanditronix Medical and its sister company Wellhöfer Dosimetrie GmbH for OmniDos, General Dosimetry System has been tested and found to fulfil the requirements concerning electromagnetic compatibility according to the standard IEC 601-1-2.

(2) Clinical tests:

Due to the fact that the system is a quality assurance device in radiation treatment not directly involved in the delivery of the treatment radiation, no clinical testing was performed.

(3) Test conclusions:

Testing of operational parameters indicates that the Scanditronix Medical OmniDos General Dosimetry System is safe, it fulfils the intended use and performs as well as or better than the previously released product RFA-300plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2001

Mr. Alf Öhman
Quality Manager
Scanditronix Medical AB
Stalgatan 14
S-754 50 Uppsala
SWEDEN

Re: K011763
Omnidos General Dosimetry System Version 6.0
Dated: May 31, 2001
Received: June 7, 2001
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Öhman:

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 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). 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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, International and Consumer 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,

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

510(k) Number (if known): K011763

Device Name: OmniDos General Dosimetry System

Indications for Use:

OmniDos is a system software utilising hardware components to measure radiation dose distribution. The hardware consists of water phantoms, air scanners, film scanners/ digitizers and single or array detectors. The hardware comes from Scanditronix Medical, the sister company Wellhöfer Dosimetry and from 3'd party vendors.
OmniDos is used to accurately analyse and handle the measured dose distribution in quality assurance purposes, for calibration of radiation devices, as input data to Treatment Planning Systems, for acceptance testing, beam tuning and in research.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
K011763

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011763

Prescription Use X OR Over-The -Counter Use_____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)