

CONFIDENTIAL

K990734

MAY 28

510(k) Summary

This summary is submitted in compliance with 21 CFR 807.92

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

Contact persons: Lars Göran Larsson
+46 18 18 08 52
or
Eva Larsten
+46 18 18 07 88

Date of preparation: 26-Feb-1999

(2) Trade name of device: DPD-12PC

Common name: Direct Patient Dosemeter

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: DPD-3 (Scanditronix Medical AB), FDA K9420921, 510(k) July 1994, DPD-510 (Scanditronix Medical AB) FDA K925133, 510(k) Jan.1993.

(4) Description of the devise:

The Scanditronix Medical DPD-12PC, Direct Patient Dosemeter is a device modification of DPD-3, Direct Patient Dosemeter, FDA K9420921, 510(k) July 1994 used for In Vivo Dosimetry in radiation therapy. It consists of a 12 channel electrometer, display unit (personal computer) semiconductor detectors, detector support, extension cable, communication cable.

(5) Intended uses:

The DPD-12PC Direct Patient Dosemeter is designed to be used to monitor radiation dosage during treatment. The DPD-12PC can also be used for quality control measurement of therapeutic radiation devices. The DPD-12PC provides multi-channel dose or dose-rate measurements utilising up to 12 semiconductor detectors. The device function is

accessed by using the keyboard on the user interface personal computer.
Measured parameters may be stores in the personal computer.

(6) Technological comparison:

The Scanditronix Medical's DPD-12PC, Direct Patient Dosemeter is a device modification of the predicate device Scanditronix Medical's DPD-3. Both devices are using the same technology.

(b) (1) Non-Clinical tests:

Comparison of operational characteristics for the Scanditronix Medical DPD-12-PC and the predicate product show similar results that are suitable for their intended purpose. To minimize potential electrical hazards, Scanditronix Medical adheres to recognized and established industry practice, and all devices are subject to final performance testing. The Scanditronix Medical DPD-12PC is designed for conformance with IEC 601-1 standards for electrical isolation and leakage current and meets electrical performance standards for CSA and UL. In addition, all semiconductor detectors fulfills the IEC-601-2-9 standard.

The electrometer of Scanditronix Medical DPD-12PC 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 (In Vivo Dosimetry) 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 DPD-12PC is safe, it fulfils the intended use and performs as well as or better than the previously released DPD-3.



MAY 28 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Eva Larsten
Quality Manager
Scanditronix Medical AB
Stalgatan 14
S-754 50 Uppsala
SWEDENRe: K990734
DPD-12PC Direct Patient Dosemeter
Dated: April 26, 1999
Received: April 29, 1999
Regulatory Class: II
21 CFR 892.5050, 892.5750, 892.5900
Prococode: 90 IYE

Dear Ms. Larston:

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 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K990734/5001

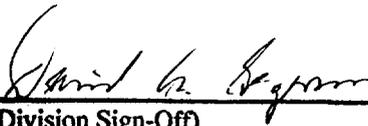
Device Name: DPD-12PC Direct Patient Dosemeter

Indications for Use:

- The DPD-12PC Direct Patient Dosemeter is used
- to monitor radiation dosage to a patient during radiotherapy procedure
 - for quality control measurements of therapeutic radiation devices

(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 K990734

Prescription Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

OR

Over-The -Counter Use _____