K993895
page 1 of 2

# 510(k) SUMMARY

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| Submitter: | PerMedics Inc. |
| Address: | 1475 S. Victoria Ct.<br>San Bernardino, CA 92408 |
| Phone number: | 909-799-8300 |
| Fax Number: | 909-799-8348 |
| Name of Contact Person: | Caroline Huff |
| Date Prepared: | November 11, 1999 |
| Device Name: | OptiRad |
| Common Name: | 3d Radiation Therapy Treatment Planning System |
| Classification Name: | System, Planning, Radiation Therapy Treatment |
| Classification Number: | CFR 892.5050 |
| Predicate Name: | ROCS TPS |

K993895
Page 2 of 2

Summary Continued:

**Description Of Device:**

The OptiRad 3D-radiation treatment planning system is a collection of software modules that execute algorithms to produce radiation dose computations (estimations). Input is user controlled. This treatment planning system does not provide direct or indirect control over any treatment delivery device or system in any form.

The OptiRad software application is intended to be used for the computation, display, evaluation, and output documentation of radiation dose estimations that are to be submitted for independent clinical review and verification by a physicist or physician prior to use.

The application provides output data in the form of displays or hardcopy printouts to guide a physician in selecting the optimum patient treatment plan. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist, dosimetrist, or radiation treatment planner.

**Intended Use Of Device:**

To be used for the computation, display, evaluation and output documentation of radiation dose estimations to be submitted for independent clinical review and judgement prior to use. The device provides output data in the form of displays and/or hardcopies to guide a physician in selecting the optimum patient treatment plan. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist or dosimetrist.

**Technological Characteristics:**

The OptiRad and the predicate ROCS TPS are the same in that they both are intended to be used for the computation, display, evaluation, and output documentation of radiation dose estimations and are to be submitted for independent clinical review and verification by a physicist or physician prior to use.

The OptiRad is designed to work in Microsoft® Windows NT® operating system as is the ROCS TPS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2000

PerMedics, Inc.
C/O Greg Holland
Regulatory Consultant
Holland & Associates
3722 Avenue Sausalito
Irvine, CA 92606

Re: K993895
OptiRad (3D Radiation Therapy Treatment Planning System)
Dated: March 17, 2000
Received: March 20, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Mr. Holland:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K993895

Device Name: OptiRad

Indications For Use:

The OptiRad software is to be used for the computation, display, evaluation and output documentation of radiation dose estimations to be submitted for independent clinical review and judgement prior to use. The device provides output data in the form of displays and/or hardcopies to guide a physician in selecting the optimum patient treatment plan. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist or dosimetrist.

(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) (Optional Format 1-2-96)

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993895