JAN 12 2005

1 of 2

PERMEDICS inc.

K047861

510(k) Summary

Submitter:
PerMedics, Inc.
1475 S. Victoria Ct.
San Bernardino, CA. 92408
Phone: (909) 478-5000
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Contact Person:
Jessica Connor
Quality Assurance Manager

Date Prepared:
October 12, 2004

Device Name:
Odyssey

Common Name:
Radiation Treatment Planning System

Classification Name:
System, Planning, Radiation Treatment

Predicate Devices:
ADAC P^3IMRT™ – K002237
OptiRad – K993895

Device Description:
The Odyssey radiation treatment planning system is a collection of software modules that execute algorithms to produce radiation dose computations (estimations). The system includes functions for imaging, target and non-target delineation, beam planning, verification and quality assurance. An earlier version of the software was known as "OptiRad" (K993895). In addition to forward planning, users who have the Intensity Modulated Radiation Treatment (IMRT) module can perform inverse planning.

Intended Use:
Odyssey is to be used for the computation, display, evaluation and output of radiation dose estimations to be submitted for independent clinical review and judgment prior to use in radiation therapy.

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Summary of Technological Characteristics Compared to Predicate Devices:

Odyssey contains no technological characteristics not currently contained in the predicate devices, ADAC P^3IMRT inverse planning option (K002237) and OptiRad (K993895).

Summary of Non-Clinical Testing:

The performance and results of Verification and Validation demonstrate Odyssey to be safe and effective. A Hazard Analysis and Failure Modes and Effects Analysis were completed, with all hazards and failure modes mitigated to acceptable levels.

Summary of Clinical Testing:

Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness of Odyssey.

Conclusion:

Odyssey is as safe, as effective, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Ms. Jessica Connor
Quality Assurance Manager
PerMedics, Inc.
1475 S. Victoria Ct.
SAN BERNARDINO CA 92408

Re: K042861
Trade/Device Name: Odyssey
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: December 9, 2004
Received: December 10, 2004

Dear Ms. Connor:

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 either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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 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:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 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

Indications for Use

510(k) Number (if known): K042861

Device Name: Odyssey

Indications for Use:

Odyssey is to be used for the computation, display, evaluation and output of radiation dose estimations to be submitted for independent clinical review and judgment prior to use in radiation therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use /

David R. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042861