JUN 1 1998

MasTek D.E.M., Inc.
1465 Cypress Avenue
Melbourne, FL 32935
Phone 1-407-253-9800
Fax 1-407-253-0423

K980826

EquiDose™ Solid State Diode Detectors
510(k) Submission

Manufacturer's 510(k) Summary, 21 CFR 807.92:

1. **Company:**

MasTek D.E.M., Inc.
1465 Cypress Avenue
Melbourne, FL 32935

Contact:

Jorge A. Fernández
Senior Vice President
MasTek D.E.M., Inc.
(P) 1-407-253-9800
(F) 1-407-253-0423

Date of Submission:
February 12, 1998

2. **Trade/Proprietary Name:**
EquiDose™ Solid State Diode Detectors

Common/Usual Name:
Diode Detectors

3. **Predicate Device(s):**
ISORAD™ Solid State Diode Detectors, which were cleared to market under 510(k) number K912250.

4. **Description of Device(s):**
MasTek's EquiDose™ Solid State Diode Detectors are classical solid state diode detectors used for verification measurements in radiation therapy. All of the diodes share the same design, manufacturing process, are made of the same materials and they are all waterproof. With the exception of their higher input impedance and standard 2 meter cable length, the EquiDose™ Solid State Diode Detectors are exactly the same as the predicate ISORAD™ Solid State Diode Detectors.

EquiDose™ Solid State Diode Detectors, when connected to an appropriate electrometer like the PTW-UNIDOS, K951764, are used to collect and verify beam data from radiation therapy treatment machines and to verify therapeutic amounts of radiation delivered during treatments.

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5. Statement of Intended Use:

EquiDose™ Solid State Diode Detectors are intended to be used for the collection of radiation beam data from radiation therapy treatment machines in air, water, or in other suitable material. The data acquired with this type of detector can be used to compile radiation beam data over time as part of a quality assurance program, to verify treatment machine energy and output, and to measure therapeutic doses delivered to patients during treatment.

6. Comparison of Technological Characteristics to the Predicate Devices:

The indications for use are exactly the same as the predicate devices, ISORAD™ Solid State Diode Detectors which were cleared to market by the FDA under K912250.

The designs are exactly the same.

The manufacturing and testing, process and procedures are exactly the same.

The materials used are the same as in the predicate devices.

The specifications are the same as the predicate devices.

The indications for use, design, materials, manufacturing, and specifications of the EquiDose™ Solid State Diode Detectors do not raise any issues with regard to safety and effectiveness. MasTek D.E.M., Inc. considers all of these solid state diode detectors equivalent to the predicate devices for radiation therapy beam data measurements.

Note: Any statement made in conjunction with this Summary regarding substantial equivalence to another product was made in relation to the 510(k) premarket approval process and should not be interpreted as an admission or used as evidence in patient infringement litigation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1998

Jorge A. Fernandez
Senior Vice President
MasTek D.E.M., Inc.
1465 Cypress Avenue
Melbourne, FL 32935

Re: K980826
EquiDose™ Solid State Diode Detectors
Dated: February 12, 1998
Received: March 3, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Fernandez:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTN: Dr Chen

510(k) Number (if known): K980826

Device Name: Equidose™ Solid State Diode Detectors

Indications For Use:

The EquiDose™ Solid State Diode Detector is intended to be used for the collection of radiation beam data from radiation-producing machines.

For use, simply place the EquiDose™ Detector inside the area where radiation shall be administered. The connector end of the detector should be attached to an electrometer that will receive the current signal produced by the detector. Through processing, this signal will then indicate the radiation quantity.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Bogen

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980826

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)