K992577

SEP 23 1999

Photoelectron Corporation's
Photon Radiosurgery System (PRS)

1. SPONSOR

Photoelectron Corporation
5 Forbes Road, Suite 2
Lexington, MA 02421-7305

Contact Person: Paul A. Pelletier
Director of Regulatory Affairs and Quality Assurance
Telephone: 781-861-2069

Date Prepared: July 30, 1999

2. DEVICE NAME

Proprietary Name: Photon Radiosurgery System (PRS)
Common/Usual Name: Miniature X-ray source with control and calibration systems and accessories
Classification Name: X-ray Radiation Therapy System and Accessories

3. PREDICATE DEVICES

The PRS and PRS Spherical Applicators are substantially equivalent to the following devices:

- Nucletron-Oldelft microSelectron-HDR brachytherapy device (K953946)
- Varian VariSource Remote Afterloader for High Dose Brachytherapy (K945383)
- Intraop Medical MOBETRON System (K981112)

6. DEVICE DESCRIPTION

The ***Photoelectron Corporation*** Photon Radiosurgery System (PRS) is a miniature, high-dose rate, low energy X-ray source that emits X-ray radiation from the tip of a 3 mm diameter probe. The original PRS Model was cleared for marketing in the 510(k) K964947. The PRS was subsequently modified and

cleared for marketing in 510(k) K980526 (PRS400). The PRS was cleared by these 510(k)s for the irradiation of intracranial tumors.

Since the currently cleared PRS400 is restricted to treatment of intracranial tumors, Photoelectron Corporation is also proposing in this 510(k) to modify the PRS indications for use to permit use of the PRS to irradiate tumors other than at intracranial locations.

This 510(k) is also being submitted to add the use of PRS Spherical Applicators to the PRS System. The Spherical Applicators will permit the PRS to be used for intracavitary or intraoperative radiation therapy. In addition, two accessories for use with the Spherical Applicators are also being added to the PRS: the Radiation Shields, which protect surrounding tissue and/or organs from radiation, and the PRS Interface Adapters, which provide a means for connecting the PRS X-ray Source (XRS), and the Spherical Applicators to various commercially available surgical support systems for non-stereotactic applications.

7. INTENDED USE

The Indications for Use for the PRS400 will be revised to read as follows:

"The Photon Radiosurgery System is intended to be used for radiation therapy treatment".

The proposed Indications for Use for the Spherical Applicators are:

"The PRS Spherical Applicators are intended to be used with the Photon Radiosurgery System (PRS) to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity or intraoperative radiotherapy treatments".

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed PRS intended use is substantially equivalent to commercially available brachytherapy and LINAC devices. All of the devices are intended to deliver a high radiation dose to tumors with low to minimal dose to healthy tissue. In addition, all of the devices have been used for treatment of tumors in a wide variety of anatomical locations, such as brain and breast tumors. All

systems provide a variety of applicators to facilitate radiation treatment in the various anatomical locations.

7.0 TESTING

Photoelectron submitted dosimetry data on the Spherical Applicators that demonstrates the uniformity of dose delivered to tumor margins.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 1999

Mr. Paul A. Pelletier
Director of Regulatory and
Quality Assurance
Photoelectron Corporation
5 Forbes Road, Suite 2
Lexington, MA 02421-7305

Re: K992577
Photelectron Radiosurgery System (PRS)
Dated: July 30, 1999
Received: August 2, 1999
Product Code: 90 JAD
Regulatory Class: II (two)
21 CFR 892.5900

Dear Mr. Pelletier:

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): K992577

Device Name: Photon Radiosurgery System (PRS)

Indications For Use:

The Photon Radiosurgery System (PRS) is indicated for radiation therapy treatments.

The PRS Spherical Applicators are indicated for use with the Photon Radiosurgery System (PRS) to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity or intraoperative radiotherapy treatments.

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992577

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