JUL 27 1998

K980526

510(k) Summary
for
Photoelectron Corporation
PRS400 PHOTON RADIOSURGERY SYSTEM

1. **Date Prepared**: February 9, 1998

2. **Submitter's Name and Address:**

Photoelectron Corporation
5 Forbes Road
Lexington, MA 02173

3. **Contact Person:**

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Director, Clinical Research and Regulatory Affairs
Photoelectron Corporation

Telephone: (781) 861-2069
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4. **Device Name:**

Proprietary Name:	Photon Radiosurgery System (PRS)
Common Name:	Miniature X-Ray Source with Control and Calibration Systems and Accessories
Classification Name:	X-ray Radiation Therapy System

5. **Predicate Device:**

The PRS400 Photon Radiosurgery System (PRS) is substantially equivalent to the PRS Model 3. A 510(k) for the PRS Model 3 was cleared by FDA on June 20, 1997 (K964947).

6. Device Description:

The PRS400 Photon Radiosurgery System is a modification of the Photoelectron Corporation PRS Model 3. Modifications have been made to increase radiation safety, improve the user interface with the system, and improve manufacturability of the PRS components. None of the changes affect the function, intended use, or overall design of the PRS. Both devices are complete systems for highly focused treatment of intracranial tumors. The heart of the system is a miniature, high dose rate, low energy X-ray source equipped with a 3.175 mm diameter, 10 cm long interstitial probe. The X-ray source is designed so that the tip of the probe can be positioned precisely into the tumor and a prescribed therapeutic radiation dose delivered in a single fraction. X-rays are emitted from the tip of the PRS' probe in a spherically symmetric pattern and the tumor is destroyed from the inside out. A sterile sheath is placed over the probe prior to insertion into the tumor. The voltage, current, and exposure time of the X-rays are set via the PRS400 Control Console. A complete set of accessories is provided to assist in placement of the interstitial probe and to perform quality control of the X-ray source in the clinical setting. Additional laboratory-based components of the PRS include an automated dosimetry water tank for calibration and a CCD-camera based radio chromic film reader for dose verification.

The key differences between the PRS400 and the PRS Model 3 are summarized below:

- The X-ray Source (XRS) is slightly larger and heavier. The circuit architecture and layout have been redesigned to permit additional functions to be built into the XRS enclosure. The probe and the output of the PRS400 XRS are essentially the same as the Model 3.

- The PRS400 Control Console has been redesigned to include an on-board microprocessor. The external lap-top computer used with the Model 3 has been eliminated. Control of the system is now menu-driven through commands entered from a front panel keypad.

- The Probe sheath used to provide a biocompatible, sterile barrier between the patient and the probe will be packaged sterile for the PRS400 instead of needing to be sterilized by the user.

7. **Intended Use:**

The intended use of the Photon Radiosurgery System is to irradiate intracranial tumors.

8. **Comparison of Technological Characteristics:**

The technological and functional characteristics of the PRS400 are essentially identical to the PRS Model 3. The changes to the PRS components incorporated in the PRS400 are refinements to their design and do not represent technological changes. The radiation source used in both models is essentially the same and produces nearly identical radiative output.

9. **Nonclinical Tests:**

Non-clinical testing conducted on the PRS included the following:

Electromagnetic Compatibility: The PRS complies with the requirements of EN 60601-1-2

In Vitro Laboratory Studies: In vitro laboratory studies were performed to compare the radiative properties of the Model 3 and the PRS400. These studies demonstrate that the PRS400 and the Model 3 produce the same output which is characterized by a low photon energy and a steep fall-off in dose with distance from the probe. The dose distribution around the probe is nearly spherical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Thomas R. Varricchione, MBA, RRT
Director, Clinical Research and Regulatory Affairs
PeC Photoelectron Corporation
5 Forbes Road
Lexington, MA 02173

Re: K980526
Photon Radiosurgery System PRS400
Dated: May 20, 1998
Received: May 21, 1998
Regulatory class: II
21 CFR 892.5900/Procode: 90 JAD

Dear Mr. Varricchione:

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

510(k) Number (if known): K980526

Device Name: Photon Radiosurgery System (PRS) PRS400

Indications For Use:

The Photon Radiosurgery System is intended to be used for the irradiation on intracranial tumors.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980526

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