K964947

JUN 20 1997

510(k) Summary for
Photoelectron Corporation
PHOTON RADIOSURGERY SYSTEM

1. **Date Prepared:** December 9, 1996

2. **Submitter's Name and Address:** *Photoelectron Corporation*
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Lexington, MA 02173 USA

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4. **Device Name:** Proprietary Name: Photon Radiosurgery System
Common Name: Miniature X-ray Source with Control and Calibration Systems and Accessories
Classification Name: X-ray Radiation Therapy System

5. **Predicate Device:**

The Photon Radiosurgery System is substantially equivalent to the Nucletron-Oldeft microSelectron-HDR interstitial brachytherapy device and the Elekta Radiosurgery Inc. Leksell Gamma Unit Model 23004.

6. **Device Description:**

The Photon Radiosurgery System (PRS) is a complete system for highly focused treatment of intracranial tumors. The PRS includes an X-ray Source and Control Box, along with accessories for clinical treatment, quality assurance, laboratory calibration and dose verification. The miniature X-ray source incorporates a 3.175 mm diameter, 10 cm long interstitial probe and is designed to be mounted on a stereotactic frame so that the probe tip, covered with a sterile sheath, can be

positioned precisely into the tumor. High dose rate, low energy X-rays are emitted from the probe tip in a spherical pattern and a prescribed therapeutic radiation dose delivered in a single fraction destroys the tumor from the inside out. Voltage, beam current, and treatment time or photon count are set on the Control Box which is powered by a rechargeable battery. Accessories are 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 radiochromic film reader for dose verification.

7. Intended Use:

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

8. Comparison of Technological Characteristics:

Technological and functional characteristics of the PRS are similar to those of interstitial brachytherapy systems with radionuclides and to external beam stereotactic radiosurgery systems (LINAC and/or Gamma Knife). Comparison of the PRS with these devices included radiation sources, methods of application, relative dose rates, dose adjustment methods, collateral radiation protection, and the exposure of healthy tissue to radiation. This discussion illustrated the PRS's similarities with technological and functional features of the predicate devices.

9. Preclinical Tests:

Several preclinical *in vitro* laboratory studies were conducted to characterize performance of the PRS, especially with regard to its output parameters and their effects. Preclinical tests also included animal studies in rats and dogs which characterized the effects of *in vitro* PRS irradiation of liver and brain tissue. *In vitro* and *in vivo* studies were also conducted to characterize the thermal properties of the PRS X-ray source. These studies demonstrated that the PRS was able to create highly demarcated areas of tissue destruction in targeted animal tissue without evidence of deleterious effects. Preclinical tests conducted on the PRS also included testing for compliance with electromagnetic compatibility and materials biocompatibility requirements.

10. Clinical Tests:

Two phases of clinical studies to evaluate the safety and effectiveness of the Photon Radiosurgery System (PRS) for irradiation of intracranial tumors were conducted over a four year period at multiple clinical sites. Studies included treatment of eligible subjects diagnosed with primary or metastatic intracranial tumors which were either solitary or multiple in number. Assessment methods used to evaluate safety and effectiveness included clinical, radiological, functional and quality of life measures. Autopsy data was also obtained and provided to FDA as direct, objective evidence of the effects of PRS irradiation in comparison with the effects of other radiation therapy devices. A summary and analysis, as well as complete patient data, were provided to FDA as evidence of the safety and effectiveness of the PRS for treatment of intracranial tumors.

11. Conclusions:

Studies performed with the Photon Radiosurgery System (PRS) demonstrate that it emits high dose rate, low energy X-ray radiation in a spherical pattern from the tip of an X-ray Source probe which can be placed inside the body. Targeted tumors can be irradiated and destroyed in a precise and controllable manner. Data provided in this 510(k) Premarket Notification demonstrates that the Photon Radiosurgery System has the same intended use, has similar technological and functional features, employs similar construction methods and materials, and is as safe and effective as legally marketed predicate devices for the irradiation of intracranial tumors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Thomas R. Varricchione, MBA, RRT
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PeC Photoelectron Corporation
5 Forbes Road
Lexington, MA 02173

Re: K964947
Photon Radiosurgery System (PRS)
Dated: April 8, 1996
Received: April 9, 1997
Regulatory class: II
21 CFR 892.5900/Procode: 90 JAD

Dear Mr. Varrichione:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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/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): K964947

Device Name: Photon Radiosurgery System

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964947

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