K082909

510(k) Summary

DEC 23 2008

510(k) Owner/Applicant:	The Phantom Laboratory, Incorporated Joshua R. Levy, President
Mailing Address:	P.O. Box 511, Salem, NY 12865
Telephone: Fax:	(518) 692-1190 (518) 692-3329
Date	September 26, 2008
Device Name:	Trade name – RSVP Half Sphere Phantom™ Classification name – Accelerator, linear, medical (892.5050, Product Code IYE)
Equivalent Device:	RSVP Phantom™ , 510(k) submission number K954634.
Device Description:	The RSVP Half Sphere Phantom™ was developed to provide localization and dose verification for radiation therapy machines, specifically the Leksell™ Gamma Knife stereotactic radiosurgery system. The phantom's design provides full simulation of the localization and irradiation sequences. The hemi-spherical shape is formed from a urethane material and filled with water to simulate the radiation absorption and scatter of human soft tissue.
Intended Use:	The RSVP Half Sphere Phantom™ is designed for verification of therapy dose delivery in radiation therapy machines, specifically the Leksell™ Gamma Knife stereotactic radiosurgery system. The phantom can also be used for periodic quality assurance evaluations and acceptance testing, and to perform reevaluations after equipment or software upgrades. The phantom works in conjunction with commercially available ion chambers, which are not manufactured by The Phantom Laboratory.
Technological Comparison:	The RSVP Half Sphere Phantom™ and the predicate device, RSVP Phantom™ , are both designed to evaluate maximum delivered dose to an identified location for radiation therapy machines. Both phantoms are formed from materials selected for strength and tissue like absorbency, filled with water to simulate human tissue, and mimic actual patient absorbed dosages.

Testing Conclusions:

This 510(k) application draws on conclusions made from the research and corresponding paper, "Calibration of the Gamma Knife using a new phantom following the AAPM TG51 and TG21 protocols" by R. E. Drzymala and R. C. Wood.

The geometric shape of the RSVP Half Sphere Phantom™ has the advantage, compared to the predicate device, of simpler theoretical calculations and easier position reproducibility which makes it ideal for consistency monitoring through periodic QA testing.

During the creation of prototypes for the RSVP Half Sphere Phantom™ , as part of the development process, numerous measurements and pressure leak tests were conducted in accordance with the Phantom Laboratory's ISO 9001:2000 registered quality system. The measurement equipment used was calibrated with traceability to NIST.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

Mr. Joshua R. Levy
President
The Phantom Laboratory, Inc.
PO Box 511
SALEM NY 12865

Re: K082909
Trade/Device Name: RSVP Half Sphere Phantom™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 28, 2008
Received: September 30, 2008

Dear Mr. Levy:

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 such 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part.807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting 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): K082909

Device Name: RSVP Half Sphere Phantom™

Indications For Use:

The RSVP Half Sphere Phantom™ is designed for verification of therapy dose delivery in radiation therapy machines, specifically the Leksell™ Gamma Knife sterotactic radiosurgery system. The phantom can also be used for periodic quality assurance evaluations and acceptance testing, and to perform reevaluations after equipment or software upgrades. The phantom works in conjunction with commercially available ion chambers, which are not manufactured by the Phantom Laboratory.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082909