

K970647

MAY 20 1997

EXHIBIT #1
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V. SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

This summary of (510k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : _____

Submitter's Identification OUR Scientific International, Inc.
1 World Trade Center, Suite 7871
New York, NY 10048

Date Summary Prepared February 18, 1997

Contact Person: Vivian Guo, President
(212) 524-9739

Name of Device: Proprietary: OUR Rotating Gamma System
Classification: Radionuclide Radiation Therapy System
Common: Gamma System

Predicate Device Information: The OUR Rotating Gamma System is substantially equivalent to the Leksell Gamma Unit Model 23004, Type B, manufactured and marketed by Elekta Instruments. The predicate device has previously obtained FDA 510(k) clearance for marketing in the United States for the treatment of selected intracranial abnormalities. The equivalence is established based on the intended use, performance specifications, materials and technical characteristics. In one technical aspect, the OUR Rotating Gamma System is equivalent to the SRS-200 system by Philips Medical Systems, Inc.

Device Description: The OUR Rotating Gamma System is a teletherapy device which contains 30 ⁶⁰Co sources distributed on a hemispheric source carrier, which is inside a hemispheric shield. Inside the source unit is the "built-in" secondary collimator, which has 4 sizes of collimators and 1 block position. When not treating a patient, all sources are aligned with the block position of the secondary collimator, which in this case acts

as a radiation shutter. Treatment starts by aligning the sources to the desired collimator size, then both the source unit and the secondary collimator rotates as one unit. By rotating the ^{60}Co γ -ray beams during treatment, 30 non-overlapping full 360° arcs are formed, resulting in high focal dose uniformity and small focal spot penumbra. The entire system consists of a) The γ -ray treatment unit, b) the stereotactic localization system, and c) the treatment planning system.

To ensure mechanical safety, the system uses redundant limit switches to detect the positions of the doors, and the couch. Low torque motors are used such that all motions can be stopped by one hand. Electrical safety is ensured by use 24VDC power in the entire treatment unit with multiple current limiting breakers. Redundant timing devices are used for treatment timing accuracy. The novel radiation shutter reduces transient radiation exposure to patient's normal structures and adds radiation safety.

Intended Use:

The OUR Rotating Gamma System is intended to be used in the treatment of selected intracranial abnormalities, previously cleared by FDA for the Leksell Gamma Knife and for the Philips SRS-200 Radiosurgery System.

Biocompatibility Assessment:

Patient-contacting materials include the screws employed in the stereotactic localization frame. Material composition of these screws consist of titanium, Specification TC 4/T-A6V/AMS 4928H which is not subject to biocompatibility testing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OUR Scientific International, Inc.
c/o Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd.
Suite 410
Great Neck, NY 11021

Re: K970647
OUR Rotating Gamma System
Stereotactic Radiosurgery Unit
Dated: February 18, 1997
Received: February 20, 1997
Regulatory Class: II
21 CFR 892.5750/Procode: 90 IWB

MAY 20 1997

Dear Ms. Goldstein-Falk:

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): _____

Device Name: OUR Scientific International, Inc.
OUR Rotating Gamma System

Indications For Use:

The OUR Rotating Gamma System is a teletherapy device intended to be used for the stereotactic irradiation of intracranial structures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K970647