K982463

SEP 30 1998

510(k) Summary

Proprietary Name:	Extracranial Radiotherapy System
Common Name:	Extracranial Radiotherapy System
Classification Name:	Stereotaxic Instrument
Reference:	21 CFR 882.4560
Proposed Regulatory Class:	II
Device Product Code:	HAW

For information contact: Vivian Kelly
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Phone: (201) 507- 7830
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Date Prepared: July 14, 1998

Summary:

The Extracranial Radiotherapy System is a device consisting of a carbon fiber table, a patient support cushion and lateral support panels, stereotaxic plates and related fasteners and assembly tools. During treatment the patient lies supine on the fitted cushion. Four stereotaxic plates surround the patient during CT imaging, with one plate between the support cushion and the table, two placed laterally and one above the patient. Target positioners on the support assembly are used to align the table with the linear accelerator coordinate axes and to verify the target point for treatment. The Extracranial Radiotherapy System is intended for stereotaxic patient positioning and localization during imaging and treatment of extracranial targets.

The table is design to be used with Leibinger's STP Complete Module Set and Marker System (K892425) and any future Leibinger software planning systems.

The subject device is substantially equivalent to the following devices: Stereotactic Body Frame (Precision Therapy International K960338, K970291), STP Complete Module/ZD Stereotaxic Frame (Leibinger K892425/D), and Marker System for Stereotaxic Navigation (Leibinger K961120). The Extracranial Radiosurgery System and the Stereotactic Body Frame are equivalent in intended use and in design in that they both include a table or rigid frame, support cushion fitted to the patient and positioning or guide mechanism reference systems used for radiotherapy treatment with linear accelerators. The Extracranial Radiosurgery System, the STP Complete Module/ZD Stereotaxic Frame and the Marker System for Stereotaxic Navigation demonstrate similar treatment accuracy during testing with CT images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1998

Ms. Vivian Kelly
Manager, Regulatory Affairs
HOWMEDICA, Inc.
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K982463
Trade Name: Extracranial Radiotherapy System``
Regulatory Class: II
Product Code: IYE
Dated: July 14, 1998
Received: July 15, 1998

Dear Ms. Kelly:

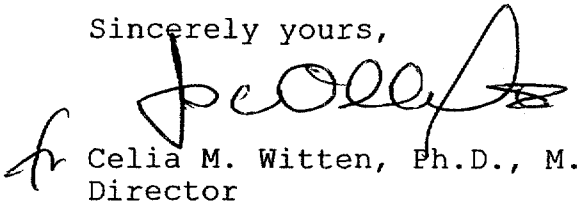
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4659. 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,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Unknown

Device Name: Extracranial Radiotherapy System

Indications for Use:

The Extracranial Radiotherapy System is intended for stereotaxic patient positioning and localization during imaging and treatment of extracranial targets.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982463