



MICK RADIO-NUCLEAR INSTRUMENTS, INC.

Tab 10

10972709

OCT 16 1997

Premarket Notification [510(k)] Summary

July 12, 1997

Trade Name: TBI Stand

Common Name: Total Body Irradiation Stand

Classification Name: Medical charged partical radiation therapy system, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Mick Radio-Nuclear Instruments, Inc.
Address: 1470 Outlook Avenue
 P.O. Box 99
 Bronx, New York 10465

Corresponding Official: Mr. Felix W. Mick
Title: President

Telephone: 718-597-3999 Fax: 718-824-8834

Predicate: MED-TEC Radio Therpay Treatment Chair,
 Number: K951947

Device Description: The TBI Stand is used to safely support and reposition a patient for radiation therapy treatment in the vertical (standing) position when physician desires to treat the patient with whole body irradiation by high energy photons or electrons, usually from a medical electron accelerator. At times, the physicians utilizes the optional Scatter Screen to increase the surface dose to the patient during photon treatment.

Intended Use: Support and permit repositioning of a vertical (standing) patient for total body radiation therapy.

Technology Characteristics: See the attached "Predicate Comparison Table" of the Mick TBI Stand and the MED-TEC Radio Therapy Treatment Chair.

Tab 10

Predicate Comparison Table

Specifications	MED-TEC Treatment Chair K951947	Mick Radio-Nuclear Total Body Irradiation Stand (TBI)
Vertical Patient Positioning	Yes, upper torso	Yes, whole body
Head Positioning	Yes	Yes
Shoulder Positioning	No	Yes
Arm Support	Yes	Yes
Hand Grips	Yes	Yes
Seat-Padded	Yes	Yes
AP/PA Treatment Positions	Yes	Yes
Transparent Back Support	Yes	Yes
Film Cassette Holder	No	Yes
Reproducible Settings	Yes	Yes
Lung Shield Supports	No	Yes
Radiation Spoiler (Scatter Screen)	No	Yes
Construction:	Wood, Plastic and Carbon Fiber	Stainless Steel, Delrin, Acrylic, Wood, Formica
Weight:	22 lbs	100 lbs
Use Location	On treatment table	Rolls on floor



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 1997

Felix W. Mick
President
Mick Radio-Nuclear Instruments, Inc.
1470 Outlook Avenue
P.O. Box 99
Bronx, New York 10465

Re: K972709
Total Body Irradiation Stand
Dated: July 13, 1997
Received: July 21, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Mick:

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) 594-4613. 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/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

Tab 11510(k) Number (if known): K972709

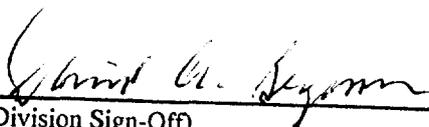
Device Name: TBI Stand

Indications for Use:

The TBI Stand is used to safely support and reposition a patient for radiation therapy treatment in the vertical (standing) position when a physician desires to treat the patient with whole body irradiation by high energy photons or electrons, usually from a medical electron accelerator. At times, the physician utilizes the optional Scatter Screen to increase the surface dose to the patient during photon treatment.

(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, ENT,
and Radiological Devices
510(k) Number K972709

Prescription Use
(per 21 CFR 801.109)

OR

Over-The-Counter Use