K050888

DIACOR, INC., 3191 SOUTH 3300 EAST, SUITE 100A, SALT LAKE CITY, UT 84109 /801-467-0050 / FAX 801-487-3258

DIACOR

Premarket Notification [510(k)] Summary

April 6, 2005

MAY 2 3 2005

Trade Name: : Integra™ Immobilization System

Common Name: Head and Neck Immobilization System

Classification Name: Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: DIACOR, Inc.
Address: 3191 South 3300 East
Salt Lake City, Utah 84109

Corresponding Official: Glenn Waterman
Title: President and CEO
Telephone: 800-342-2679
Fax: 801-487-3258

Predicate: Orfit Industries Raycast Immobilization Systems and Thermoplastics, K991319

Device Description: The Integra Immobilization System consists of three device options which may be used as the patient simulation and treatment circumstances indicate. All three options of the System utilize the same thermoplastic, all three are designed with high strength carbon fiber, with foam core to provide a strong but light weight support base and all three provide head, neck and shoulder immobilization for patients undergoing simulation or radiation therapy using the exact same attachment of the thermoplastic to the carbon fiber board.

The "*Integra ce* Extension" option to the Varian Exact Couch provides a means to attach the extension securely to the end of the Exact Couch utilizing Varian's end of table design. The board provides rigid support to the head and shoulders by means of its carbon fiber and foam core construction.

The "*Integra ci* Insert" option to the Varian Exact Couch provides the means to provide head, neck and shoulder immobilization on a CT Scanner couch or a Varian Exact Treatment Table. This insert fits into a mating recess in the CT table overlay or a similar insert space in the Exact Treatment Table.

The "*Integra co* Cantilever Board" option provides head, neck and shoulder immobilization as part of a stand alone carbon fiber and foam core board. The board

is constructed utilizing carbon fiber surfaces with a foam interior. The result is an extremely stong but light weight board. The overall design of the board provides comfortable patient support and a means to index the board to the table or overlay that it rests upon.

The Integra Immobilization System utilizes the method of head, neck and shoulder fixation that is also commonly found in radiation therapy departments and has been repeatedly shown to be safe and effective in immobilizing the head, neck and shoulders. The thermoplastic from Orfit is heated in a water bath to a temperature that makes the thermoplastic moldable. The material is removed from the bath, dried and placed over the patients head, neck and shoulders. It is stretched over the head, neck and shoulders, molded to conform to the patients head, neck and shoulder contour and attached to the support board in such a way that the patient is firmly held in place and yet can be released from the position very quickly if needed. As the thermoplastic cools, it hardens and thus permanently maintains the patient contour for repeated identical immobilizations required during a course of treatment.

Intended Use: The Integra Immobilization System is intended to immobilize the head, neck and shoulders of the patient during radiation therapy simulation or treatment.

Technological Characteristics: See the attached Predicate Comparison Table

Predicate Comparison Table

#	Feature	Orfit Industries Thermo-plastic and Hardware, K991319	Diacor, Inc. Integra Immobilization System
1.	Intended Use	The Raycast Immobilization Systems Hardware and Thermoplastic Materials are used to retain and reproduce a patient's position during radiation therapy.	The Integra Immobilization System is intended to immobilize the head, neck and shoulders of the patient during radiation therapy simulation or treatment
2.	Carbon Fiber Over Foam Core Board Construction	HPL and Carbon Fiber Over Foam Core Board Construction	Carbon Fiber Over Foam Core Board Construction
3.	Thermoplastic Head Immobilization	Yes	Yes
4.	Head and Neck Restraint	Non-invasive thermoplastic mask	Non-invasive thermoplastic mask
5.	Head Positioning	Head Holder and Foam Wedges	Head Holder and Foam Wedges
6.	Thermoplastic Mask Release	Foam Insert to Hold Mask in Slot	Foam Insert to Hold Mask in Slot

The Diacor *Integra* Head and Neck Immobilization boards are substantially equivalent to the Orfit boards in construction, form and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2005

Mr. Glenn Waterman
President and CEO
DIACOR, Inc.
3191 South 3300 East
Suite 100A
SALT LAKE CITY UT 84109

Re: K050888
Trade/Device Name: Integra Immobilization System
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 6, 2005
Received: April 7, 2005

Dear Mr. Waterman:

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 (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 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number: K050888

Device Name: Integra Immobilization System

Indications for Use:

To enable head and neck immobilization for patient placement during radiation therapy planning and treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050888

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)