K072898

medical intelligence

PREMARKET NOTIFICATION

OCT 25 2007

510(k) SUMMARY

1.	Applicant:	Medical Intelligence Medizintechnik GmbH
2.	Address:	Robert-Bosch-Straße 8 86830 Schwabmünchen Germany
3.	Contact Person:	Michael Wolff Tel. +49 (0) 8232 9692-701
4.	Preparation Date:	July 24, 2007
5.	Device Submitted:	HexaPOD™ evo RT Couch Top
6.	Proprietary Name:	HexaPOD™ evo RT CouchTop
7.	Common Name:	Hexapod
8.	Classification Name:	Powered radiation therapy patient support assembly Product Code JAI
9.	Substantial Equivalence:	The HexaPOD is substantially equivalent to the following legally marketed device: Medical Intelligence's "HexaPOD RT Couch Top". The characteristics of this device are similar to those of the predicate device identified on the comparison chart, which is provided with the premarket notification submission. It is our opinion that the HexaPOD does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The HexaPOD evo consists of two platforms, which are connected by six length adjustable elements which are powered. By appropriate coordinative adjustment of these elements, the system is able to move the upper platform relative to the lower one. The movement can occur in all three dimensions in space. Additionally the upper platform can rotate around these three axes which results in a tilt or a rotation of the upper platform relative to the lower one. Finally an accurate positioning within all six degrees of freedom (6DOF) can be provided. The HexaPOD consists of a controller unit which is directed by a cable connected hand control. Additionally it can be directed via an external graphics user interface (GUI) which is installed on a PC.

11.	Intended Use:	The intended use of the device is to support and aid in positioning a patient during radiation therapy.
12.	Summary of the Product Change:	The only modification made to the product are the following evolutionary hardware changes: • Hardware redesign of the HexaPOD module to decrease total height of the couchtop o Carbon fibre tabletop is connected directly to the six actuators o Different type of actuators o Active brakes o Actuator motor electronic moved to controller box • Hardware redesign of the HexaPOD module to increase Safe Workload to 250 kg o Different type of actuators o Connection to table base is accomplished by screws • The centre of coordinate system of the HexaPOD is shifted 100 mm longitudinally to the gantry: change in controller software. • Mode of operation: continuous
13.	Summary of the Product Similarities to Predicate Device	The HexaPOD is identical with the predicate device concerning: • Intended use • Behaviour of movement • Software interface to external control device
12.	Biocompatibility:	The HexaPOD evo is not in direct contact with the patient. At any time when in use a sheet is to be placed between the patient´s skin surface and the treatment support when in use. Additionally there are no new materials introduced in the manufacture of the HexaPOD. Therefore, no biocompatibility studies were undertaken for this device.
13.	Performance Data:	No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2007

Medical Intelligence Medizintechnik GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

Re: K072898
Trade/Device Name: HexaPOD™ evo RT Couch Top
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: JAI
Dated: October 9, 2007
Received: October 11, 2007

Dear Mr. Preiss:

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (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,

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

Indications for Use

510(k) Number (if known): K072898

Device Name: HexaPOD™ evo RT Couch Top

Indications For Use: The intended use of the device is to support and aid in positioning a patient during radiation therapy.

Prescription Use _Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K072898