ONCOlog MEDICAL

K090044

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JAN 22 2009

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

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Correspondent:	Hans Dahlin and Jan Törnqvist

New Device Name:

Trade/Proprietary Name:	PatLog 1.0.
Common/Usual Name:	Radiotherapy Patient Handling System
Classification Name:	Medical charged-particle radiation therapy system
Classification:	21 CFR 892.5050, Product Code IYE Class II

Legally Marketed Device(s)

Our new device is based on the legally marketed device cited in the table below:

Manufacturer	Device	510(k) #
Precision Therapy International/ Precitron AB Sweden	Hercules Radiation Therapy Couch and ATLAS Couch Top	K950061
Philips Medical Systems North America Co	Intera 1.5 T MRI	K030520

14.1. Device description

The PatLog 1 0 Patient Handling System is a combination of separate components that facilitates setup of the patient on a Patient Table Plate, transport to diagnostic devices, and/or to the treatment room and back after the treatment The Patient Table Plate is docked on the patient table bases at each unit and undocked for the transport between stations with the Transport Trolley

The system consists of the following components

- Patient table plate
- Docking unit
- Transport trolley

14.2. Intended use

System for patient positioning and fixation on the treatment couch, including transportation of the patient from preparation site and/or diagnostic surveys to the treatment unit

Intended User The PatLog Patient Handling System is intended to be used by qualified radiotherapy personnel trained in using the device

14.3. Technological characteristics of the Predicate Devices

The Philips Intera MRI have a table top suitable for MR examinations – as the PatLog table top

The Hercules Radiation Therapy Couch is an electrically powered adjustable couch intended to support patients during radiation therapy The Hercules main frame consists of a T-shaped base with two vertical lifting columns The frame rests on three wheel pairs, one in each corner Each wheel pair consists of two driving wheels with one motor each The wheel pairs can turn freely around a vertical axis between the wheels

The Atlas couch top consists of a base section that is bolted to the consols at the lifting columns, and a top section connected to the base section with two C-arms that can be turned 270 degrees The C-arms provide a 650 mm long free opening for irradiation from any angle and have brakes for locking in the selected position

The ends of the couch have rollers for the polyester belt that supports the patient across the free opening The roller at the base section is fixed and contains the belt drive motor The roller at the top section adjusts the tension of the belt

There are 8 automatic, i e computer controlled modes for Hercules The lift and the Atlas belt motions do not require computer assistance for proper function

The Hercules couch has a backup system that permits local control of the couch without use of the computer A separate battery charger transformer isolates the couch from the mains supply and provides ±18V DC to the regulators in the couch for charging the batteries The couch is powered by four 12V lead-acid batteries

14.4. Summary of Technological Characteristics and Intended Use

The technological characteristics and the intended use are substantially the same for Pat-Log Patient Handling system as for Hercules Radiation Therapy Couch and ATLAS Couch Top

Name Hans Dahlin
Title CEO
ONCOlog Medical QA AB
Uppsala, Sweden

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 22 2009

ONCOlog Medical QA AB
% Mr. Casey Conry
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Re K090044
Trade/Device Name PatLog 1 0
Regulation Number 21 CFR 892 5050
Regulation Name Medical charged-particle radiation therapy system
Regulatory Class II
Product Code IYE
Dated December 31, 2008
Received January 7, 2009

Dear Mr Conry

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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 Manufactures, 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.suppot/index html

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K090044

Device Name PatLog 1 0

Indications for Use

System for patient positioning and fixation on the treatment couch, including transportation of the patient from preparation site and/or diagnostic surveys to the treatment unit

Intended User

The PatLog Patient Handling System is intended to be used by qualified radiotherapy personnel trained in using the device

Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 subpart D) (Part 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 K090044