ONCOlog MEDICAL

K092939

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OCT - 9 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):

Company name:	ONCOlog Medical QA AB
Registration number:	10026961
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Correspondent:	Hans Dahlin and Jan Törnqvist

New Device Name:

Trade/Proprietary Name:	PatLog 2.0.
Common/Usual Name:	Radiotherapy Patient Logistics 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) #
ONCOlog medical QA AB	PatLog 1.0	K090044
Precision Therapy International, Precitron AB/Sweden	Hercules Radiation Therapy Couch and ATLAS Couch Top	K950061

Device description

The PatLog 2.0 Patient Logistics System is a combination of separate products that together form a complete patient logistics system for a radiation therapy department. The Loading Station facilitates loading and initial setup of the patient on a Patient Table Plate, the Transport Trolley provides transport from the Loading Station to diagnostic devices like CT or MR, further to the Radiation therapy treatment room and back to the Loading Station for unloading after the treatment.

The Patient Table Plate is docked on the patient table bases at each unit, CT, MR or Proton Gantry, and undocked for the transport between stations with the Transport Trolley.

The system has the following components:

- **Patient Table Plates** are manufactured from radiotranslucent, non-magnetic and non-conductive composite material to be suitable both for CT, MR, X-ray and Proton therapy. They are extremely stiff and rigid and provide very precise patient positioning and reliable support during all the procedures. They have a docking mechanism for secure and precise connection to the Docking Units on all the table bases at the diagnostic and therapy units. They also have indexing features for accurate positioning and repositioning of patient immobilization devices.
- **Transport Trolleys** provide easy transport between the Patient Loading Station and the different patient table bases. The trolleys are designed to hold the Patient Table Plate securely during transport and easily disconnect and reconnect at Docking Stations. The Transport Trolleys are motorized and have a steering support system to make the transport safe and easy without twitches and jerks e.g. through narrow passages.
- **Patient Loading Stations** speed up the patient loading process and provides a reproducible transfer of the patient from standing up to horizontal position.
- **Docking Units** are mounted on each of the patient table bases at CT, MR, Simulator and Proton Therapy Units. They have features for quick and secure connection of the Patient Table Plates to each one of the patient table bases. The Docking Units are custom designed for each type of device, the Patient Positioning System (PPS) on the Proton Therapy Unit and the different table bases at the CT and MR units.

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.

Summary of Technological Characteristics and Intended Use

The technological characteristics and the intended use are substantially the same for the new PatLog 2.0 Patient Logistics System as for PatLog 1.0 and Hercules.

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

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT - 9 2009

Oncolog Medical QA AB
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

Re: K092939
Trade/Device Name: PatLog 2.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 18, 2009
Received: September 24, 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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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 K092939

Device Name PatLog 2.0.

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 K092939