JAN 3 0 2012 K111332

510(k) Summary

December 28, 2011

Trade/Device Name:	**Clarity™ OBP System**
Common Name:	Patient positioning system, ultrasound
Regulation/Classification Name:	Medical charged-particle radiation therapy system (21 CFR 892.5050, Product Code IYE)
	Radionuclide radiation therapy system (21 CFR 892.5750, Product Code IWB)
	Radiation therapy simulation system (21 CFR 892.5840, Product Code KPQ)
Regulatory Class:	Class II
Review Panel:	Radiology
Submitter/Manufacturer:	Elekta Ltd.
Establishment Registration No:	3004747535
Address:	2050 Bleury, Suite 200 Montreal, Quebec, Canada H3A 2J5 Tel: (+1) 514.985.2442 Fax: (+1) 514.985.2662
Contact:	Tony Falco, PhD

Introduction

This 510(k) Summary has been prepared in accordance with 21 CFR 807.92. It summarizes device safety and effectiveness information to provide an understanding of the basis for a determination of substantial equivalence of the *Clarity™ OBP System*.

Predicate Device Information

The *Clarity™ OBP System* is substantially equivalent to the following legally marketed devices in the United States:

- *Restitu™* (K041937; Nov 16, 2004; Product Codes: IYE, IWB, KPQ) – Resonant Medical Inc.
- *IKOEngelo™* (K083591; Dec 29, 2008; Product Code: KPQ) – IKOEtech, LLC
- *MIM 4.1 (SEASTAR)* (K071964; Sep 26, 2007; Product Code LLZ) – MIMvista Corporation

Intended Use

The *Clarity™ OBP System* is intended for use in external beam radiation therapy, to provide 3D ultrasound and hybrid imaging of soft-tissue anatomy to support radiation therapy simulation and planning, and to guide patient positioning prior to the delivery of treatment.

Device Description

The *Clarity™ OBP System* integrates medical diagnostic ultrasound and optical position tracking to acquire and reconstruct three-dimensional ultrasound (3DUS) images of soft-tissue anatomy for use in external beam radiation therapy. During the course of radiation therapy, the *Clarity™ OBP System* offers a non-ionizing means for daily localization of target anatomical structures.

The *Clarity™ OBP System* comprises the following functional components:

- The 3DUS imaging station (typically one in the CT-simulation room and one in the treatment room), including the 3DUS console with an integrated computer system and optically-tracked ultrasound probes, patient/couch position tracking tools, and a ceiling-mounted optical tracking system.
- A multimodality phantom, for 3DUS image calibration to the room's coordinate system defined by the corresponding room lasers, and for daily verification of system integrity.
- One or more dedicated workstation computer systems for multimodality image fusion and review, soft-tissue structure definition, approval of patient positioning references, and monitoring of treatment progress.
- A dedicated central server computer system (typically combined with a workstation), which houses the patient database and provides for interoperability with other imaging and treatment planning/simulation systems using the DICOM 3/RT protocol.

All networked *Clarity™ OBP System* stations are configured to run the same software version. The software interface is designed to 'walk' the user through a sequence of steps (or "course") to acquire 3DUS scans in the planning position, import planning CT data and fuse with 3DUS, define the structure of interest and approve a baseline positioning reference, acquire another 3DUS in the treatment position to determine target displacement relative to the baseline planning-day position, and adjust patient positioning prior to treatment. The 3DUS data may be exported through DICOM to a third-party virtual simulator or treatment planning system (TPS).

Different courses are defined in the software (e.g., "Prostate", "General", "QC") to help classify patients in the database and to present the user with default choices and settings, tailored for the target anatomy (e.g. prostate, bladder, liver, uterus & cervix, breast, head & neck) and daily QC tasks. Such configurations include probe type, scan settings, contouring and assisted segmentation tools, and alert values for large target misalignments.

The *Clarity™ OBP System* provides the option for hand-held ultrasound scanning or automated scanning with a motorized probe. The user can select the probe and scanning method that is most appropriate for the given target anatomy and the patient's clinical presentation. The autoscan probe comes with a probe holder apparatus and a remote control console, specifically designed to facilitate transperineal imaging of the prostate and surrounding soft tissues.

The *Clarity™ OBP System* also includes an optional web-based interface for remote review of treatment session data and positioning reference images.

Comparison with Predicate Devices

The *Clarity™ OBP System* incorporates software and system engineering improvements that have been implemented since the first release of the *Restitu™* device (K041937), aiming to improve device usability and reinforce device safety. System engineering changes include the integration of a high-performance computer system and technologically advanced diagnostic ultrasound in the 3DUS Console, and the use of passive optical tracking technology. The current system offers the option for automated scanning with a motorized (autoscan) probe, as well as for traditional manual scanning with hand-held ultrasound probes offered by the predicate device. The current components have the same intended use and are manufactured to the same recognized safety standards and regulatory requirements as those in the predicate device.

Improvements to the software interface include predefined "courses" tailored for the target anatomy and daily QC tasks, advanced editing tools for image registration and fusion, dedicated workspaces for structure contouring and definition of positioning references, and a web-based interface for remote review of patient data. Multimodality image co-registration and fusion-visualization capabilities, equivalent to those cleared for use with the *IKOEngelo™* (K083591) and *MIM 4.1 (SEASTAR)* (K071964) software devices, have been added to assist with contouring and definition of a positioning reference.

Despite the technological differences, the *Clarity™ OBP System* is substantially equivalent with the predicate devices in design, functions, and operating principles for the intended use, and does not raise new questions of safety or effectiveness.

Verification and Validation Testing

To address any potential safety and effectiveness concerns with the integration of the new technology in the *Clarity OBP System*, we have performed a systematic review and verification of design requirements and validation of essential performance, following a comprehensive hazard analysis and risk assessment process in compliance with regulatory guidance and recognized consensus standards. Software and system testing has been conducted in house and in clinical settings under conditions of simulated use. The verification and validation test results demonstrate that this next-generation device fulfills design and risk management requirements, and performs well in accordance with established specifications for its intended use.

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

Dr. Tony Falco, PhD
Official Correspondent
Elekta, Ltd.
2050 Bleury, Suite 200
MONTREAL QUEBEC H3A 2J5
CANADA

JAN 30 2012

Re: K111332
Trade/Device Name: Clarity™ OBP System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, IWB, and KPQ
Dated: December 28, 2011
Received: January 3, 2012

Dear Dr. Falco:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K111332

Device Name: Clarity™ OBP System

Indications for Use:

The Clarity™ OBP System is intended for use in external beam radiation therapy, to provide 3D ultrasound and hybrid imaging of soft-tissue anatomy to support radiation therapy simulation and planning, and to guide patient positioning prior to the delivery of treatment.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 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)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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