K041937

NOV 16 2004

510(k) Summary

Date prepared: July 16, 2004

Submitter/Owner: Resonant Medical Inc.
460 Ste-Catherine West, Suite 805
Montreal, Quebec
H3B 1A5

Contact person: Sean M. Curry
16787 Bernardo Center Drive, Suite A-1
San Diego, CA
Phone number: (858) 675-8200
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Proprietary name: RESTITU™

Common name: Patient Positioning System, Ultrasound

Classification: Class II, 892.5050, 5750, 5780, or 5840

Substantial equivalence claimed to:

1. K981424 – NOMOS Corporation, BAT® Ultrasound Localization and Positioning System
2. K032100 – Computerized Medical Systems, Inc., I-Beam
3. K030981 – Varian Medical Systems, Inc., Eclipse
4. K923851 – Phillips Medical Systems, Inc., ACQSIM Simulator/Localizer

Description:

The RESTITU system integrates medical diagnostic ultrasound systems, position sensing optical tracking systems, graphics workstations and other parts used to link these components together.

RESONANT's RESTITU is a 3D ultrasound-based image-guidance system that utilizes an ultrasound device, an optical camera tracking device and software platform to produce high quality data needed to perform accurate patient positioning and tumor localization.

RESTITU provides the capability to acquire high quality volumetric data before or after a treatment delivery fraction providing a strong set of data for treatment plan-delivery comparison studies. The RESTITU system can be integrated in any radiotherapy planning or treatment room for treatment verification. The RESTITU system resides in both the CT-

Sim and LINAC rooms and can be fully integrated into a comprehensive data and image network.

Intended use:

RESTITU is intended for use in external beam Radiation Therapy (RT) / Radiosurgery (RS) to locate internal anatomy that moves relative to external or bony landmarks, so as to position that anatomy correctly for delivery of conformal radiation.

In both the radiotherapy planning and treatment rooms, the RESTITU system is used to acquire 2D U/S image slices with the integrated ultrasound system, and to match each of these 2D slices with 3D position and orientation information obtained from the optical tracking component. In addition, the system also accomplishes the following tasks:

1. Enable users to segment anatomical structures from the 3D U/S volume data set;
2. Calculate the position and shape of a segmented anatomical structure;
3. Calculate the vector and magnitude of the displacement between two anatomical structures obtained from two 3D data sets acquired at different times;
4. Enable users to contour anatomical structures from the 3-D ultrasound volume set or 2-D ultrasound image slices;
5. Track position of treatment couch to verify patient position.

Summary of technological characteristics compared to Predicate Devices:

The RESTITU™ system has a ceiling mounted optical tracker for measuring position and orientation as opposed to an attached robotic mechanical sensing arm or camera that the predicate devices use. The RESTITU™ system is similar in design, construction, materials, intended use, and performance characteristics to the predicate device. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2004

Resonant Medical, Inc.
% Mr. Sean M. Curry
Chief Operating Officer
Certified Software Solutions
16787 Bernardo Center Drive, #A-1
SAN DIEGO CA 92128

Re: K041937
Trade/Device Name: Restitu™
Regulatory Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Number: 21 CFR 892.5840
Regulatory Name: Radiation therapy Simulation system
Regulatory Class: II
Product Code: 90 IYE, IWB, and KPQ
Dated: October 22, 2004
Received: November 10, 2004

Dear Mr. Curry:

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

510(k) Number (if known): K041937

Device Name: RESTITU™

Indications for Use:

RESTITU™ can be used for the positioning of patients that are prescribed external beam radiation treatments to organs which are readily identifiable on ultrasound images.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

David G. Lyman

Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041937