K080726

5.0 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

MAY 14 2008

This 510(k) Summary of Safety and Effectiveness is provided in accordance with 21 CFR 807.92.

Date of preparation: March 13, 2008

Submitter information:

Calypso® Medical Technologies, Inc.
2101 Fourth Avenue, Suite 500
Seattle, WA 98121

Phone: 206-254-0600
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Contact: Sue Ridge
Regulatory Affairs/Quality Systems Manager

Device trade name: Calypso® 4D Localization System

Common name: Patient localization system

Classification name: Accelerator, Linear, Medical

Classification: CFR 892.5050
Class II
Product code – IYE

Predicate devices: Calypso® 4D Localization System
(K060906)

RadioMed™ Soft Tissue Marker
(K031206)

Indications for Use:
The Calypso® 4D Localization System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Calypso® System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders.

Beacon® transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures.

Permanent Beacon® transponders are indicated for permanent implantation in the prostate and the peri-prostatic tissue.

Device Description:
The Calypso 4D Localization System (Calypso System) utilizes non-ionizing electromagnetic and optical technology to provide accurate, objective, and continuous localization of a treatment target for patient alignment and target position monitoring during radiation therapy. Use of the Calypso System for target localization is based on the system's detection of non-ionizing electromagnetic signals from passive implanted markers, called Beacon transponders. The Beacon transponders are implanted in or near the treatment target. When used with the Calypso System, the Beacon transponder signals enable objective measurement of the location of the treatment target in 3 dimensions. The system operator uses this information to align the patient's treatment target to the isocenter of the linear accelerator prior to treatment. This information can also be used to monitor (track) the position of the treatment target during radiation therapy treatment.

Summary of Performance Testing:
Performance testing demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Ms. Sue Ridge
Regulatory Affairs/Quality Systems Manager
Calypso® Medical Technologies, Inc.
2101 Fourth Avenue, Suite 500
SEATTLE WA 98121

Re: K080726
Trade/Device Name: Calypso 4D Localization System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 13, 2008
Received: March 19, 2008

Dear Ms. Ridge:

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): K080726

Device Name: Calypso® 4D Localization System

Indications For Use:

The Calypso® 4D Localization System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Calypso® System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders.

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Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K080726