K101979

FEB - 9 2011

510(k) Summary
(as required by 21 CFR 807.92(c)]

I. Submitted by:

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II. Contact Person:

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III. Date 510(k) Summary Prepared:

July 7th, 2010

IV. Name of the Device:

Proprietary Name: Explorer™ Liver --- Passive Tracking
Common / Usual Name: Computer-assisted, image-guided stereotaxic system
Classification Name: Stereotaxic Instrument (per 21 CFR 882.4560)

V. Substantial Equivalence:

The technological characteristics and indications for use of the ***Explorer™ Liver --- Passive Tracking*** are the same or similar to those found in the predicate devices. The patient contact components and component materials in both the new and predicate devices are equivalent. The packaging materials, packaging configurations, sterilization methods, and sterility assurance levels are also equivalent. The ***Explorer™ Liver --- Passive Tracking*** is substantially equivalent to the following FDA cleared frame stereotaxic systems:

1. Explorer™ (previously known as Linasys) Liver Image Guided Surgery System [K071063 & k093494]

2. Medtronic Navigation StealthStation and its Passive Instrument Option [K954276 & K972398]

3. InnerOptic InVision System [K083728]

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VI. Device Description:

The ***Explorer™ Liver --- Passive Tracking*** is an image-guided surgery medical device specifically designed to aid physicians during open liver procedures. The device is capable of mapping the current surgical position of tracked instruments onto preoperative, patient-specific MRI or CT medical images. These images can then be used as a guide by the physician for more accurate localization of tumors and other surrounding anatomic structures during liver surgery. The ***Explorer™ Liver --- Passive Tracking*** system consists of eight (8) components which are listed below:

(1) An image-guided surgery software platform installed on a personal computer (PC)
(2) An optical position sensor --- the Polaris Spectra or Vicra that can accurately localize the tracked devices listed below ***in passive tracking mode***
- A passive tracked abdominal reference (used for definition of coordinate and instrument calibration)
- A passive tracked Localization Pen Probe
- A passive tracked Laser Range Scanner (LRS)
- Two passive tracked adapters (can be attached onto up to two rigid surgical instruments simultaneously and used for their localization in 3-D surgical space)

(3) An LCD display monitor.

VII. Performance Data:

Validation and verification studies through bench tests were conducted to evaluate the performance characteristics of the ***Explorer™ Liver --- Passive Tracking*** system. The results of these studies demonstrate that the device is capable of safely and accurately performing the stated intended use. The results also show similar effectiveness to the ***Explorer™ Liver*** system (active tracking) [K071063 & k093494].

VIII. Indications For Use:

The ***Explorer™ Liver --- Passive Tracking*** device is indicated for open liver surgical procedures where image-guidance may be appropriate and where the patient can tolerate long apneic periods under general anesthesia.

IX. Device Modifications through this special 510(K) submission

The modification on the subject device (***Explorer™ Liver --- Passive Tracking***) over the previous cleared device (K071063 & k093494) through this special 510(K) submission is changing the tracking mode from active to passive. This device modification resulted in subsequent changes to the hardware, including the position sensor and the design of the tracked instruments. By replacing the active Localizer component in the software system with a passive Localizer component, the subject device is allowed to recognize each passive tracked instrument with its unique rigid body design.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Pathfinder Therapeutics, Inc.
% Dr. Senhu Li
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Re: K101979
Trade/Device Name: Explorer™ Liver - Passive Tracking
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OEW
Dated: January 14, 2011
Received: January 18, 2011

Dear Dr. Li:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101979

Indications for Use

510(k) Number (if known):

Device Name: Explorer™ Liver --- Passive Tracking

Indications For Use:

The Explorer™ Liver --- Passive Tracking device is indicated for open liver surgical procedures where image-guidance may be appropriate and where the patient can tolerate long apneic periods under general anesthesia.

Prescription Use__X__ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101979