K071063

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

I. Submitted by:

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2969 Armory Dr.
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Nashville, TN 37204

DEC 2 0 2007

II. Contact Person:

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III. Date Initial Summary Prepared:

March 5, 2007

IV. Name of the Device:

Proprietary Name: Linasys Image-Guided Liver Surgery System
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 Linasys Image-Guided Liver Surgery System 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 Linasys system is substantially equivalent to the following FDA cleared frame stereotaxic systems:

1. Medtronic Navigation StealthStation with Advanced Contour Registration Software Module [K954276 & K030106]

2. BrainLAB VectorVision2 Image Guided Surgery System with z-touch device [K983831& K003268]

3. J&J ACUSTAR I Advanced Surgical Navigation System [K944612]

VI. Device Description:

The Linasys (**Li**ver **Na**vigation **Sys**tem) 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 Linasys system consists of six (6) components which are listed below:

(1) An image-guided surgery software platform installed on a personal computer (PC)
(2) A three lens active-based optical position sensor that can accurately localize the tracked devices listed below
(3) A tracked localization probe
(4) A tracked fixed reference emitter used to define 3-D surgical space
(5) A tracked laser range scanner
(6) An LCD display monitor.

VII. Performance Data:

Validation and verification studies were conducted to evaluate the performance characteristics of the Linasys Image-Guided Liver Surgery System. The results of these studies demonstrate that the device is capable of safely and accurately performing the stated intended use.

VIII. Indications For Use:

The Linasys 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Pathfinder Therapeutics, Inc.
% James D. Stefansic, PhD, MBA
Chief Technology Officer
2969 Armory Drive, Suite 100A
Nashville, Tennessee 37204-3717

Re: K071063
Trade/Device Name: Linasys Image-Guided Liver Surgery System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OEW
Dated: November 20, 2007
Received: November 21, 2007

Dear Dr. Stefansic:

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 (240) 276-0115. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071063

Device Name: Linasys Image-Guided Liver Surgery System

Indications For Use:

The Linasys 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 General, Restorative, and Neurological Devices

510(k) Number K071063