

SEP 22 2008



**PLANISIGHT LINASYS™ LIVER SURGICAL PLANNING  
SOFTWARE  
510(k) SUMMARY  
[as required by 21 CFR 807.92(c)]**

**I. Submitted by:**

Pathfinder Therapeutics, Inc.  
2969 Armory Drive, Suite #100A  
Nashville, TN 37204

Establishment Registration Number: 3006587863

**II. Contact Person:**

James Stefansic, PhD, MBA  
Chief Technology Officer  
Telephone: (615) 783-0094  
Fax: (615) 783-0554  
E-mail: jds@2pti.com

**III. Date Summary Prepared:**

July 31, 2008

**IV. Name of the Device:**

Proprietary Name: PlaniSight Linasys™  
Common / Usual Name: Liver Surgical Planning Software (LSPS)  
Classification Name: Radiological Image Processing System (per 21 CFR 892.2050) [Class II, Product Code LLZ]

**V. Substantial Equivalence:**

The characteristics and indications for use of the PlaniSight Linasys™ device are the same or similar to those found in the predicate devices. The device is substantially equivalent to the following FDA cleared Radiological Image Processing Systems:

1. IQQA Liver Software (EDDA Technology, K061696)
2. MeVis Liver Analyzer / Liver Viewer Software (MeVis-Center for Medical Diagnostic Systems and Visualization, K051528)

**VI. Device Description:**

The PlaniSight Linasys™ Liver Surgical Planning Software (LSPS) is a self-contained, PC-based and non-invasive software application that imports medical images (CT or MRI scans) in a DICOM format. Like the predicate devices, Linasys™ LSPS is used to analyze data for preoperative planning in liver surgery. It can also output the image and model data for the use of other device, such as SurgiSight Linasys™ Image Guided Liver Surgical System (IGLSS).

Linasys™ LSPS contains dedicated functions to prepare the image data and define fiducial points for use with the SurgiSight Linasys™ IGLSS system. The LSPS device also includes dedicated functions for segmentation and modeling of organ, tumor, intrahepatic vasculature, and surgical resection planes. Quantitative measurements of functional and residual liver volume allow surgeons analyze the case and make optimal liver surgical plans.

Linasys™ LSPS consists of five (5) functions:

1. Viewing image volumes & models
2. Image volume conversion
3. Anatomic fiducial point definition
4. Segmentation & modeling
5. Surgical analysis & planning

**VII. Performance Data:**

Validation and verification studies were conducted to evaluate the performance characteristics of the Linasys™ LSPS. The results of these studies demonstrate that the device is capable of safely and accurately performing the stated indication for use.

**VIII. Indications For Use:**

The PlaniSight Linasys™ device is intended for liver surgery preoperative planning. The medical image data utilized is derived from various sources, including CT and MRI scanners. The software provides tools for 3-D visualization and volume measurement of structures in the liver following manual or semi-automatic segmentation of the liver organ, intrahepatic vessels, and physician-identified lesions. Preoperative evaluation of specific surgery strategies is supported by the feature to interactively define virtual resections that divide the liver and calculate margins around lesions. Data can be exported in a format suitable for image-guided surgery with the SurgiSight Linasys device. Typical users of the software are trained professionals, including physicians, nurses, and technicians.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 22 2008

James D. Stefansic, Ph.D., MBA  
Chief Technology Officer  
Pathfinder Therapeutics, Inc.  
2969 Armory Drive Suite 100A  
NASHVILLE TN 37204

Re: K082228

Trade/Device Name: PlaniSight Linasys™ Liver Surgical Planning Software (LSPS)  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: August 5, 2008  
Received: August 7, 2008

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(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 Biometrics' (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,



Joyce M. Whang, Ph.D.  
Acting 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): K082228

Device Name: **PlaniSight Linasys™ Liver Surgical Planning Software (LSPS)**

### Indications For Use:

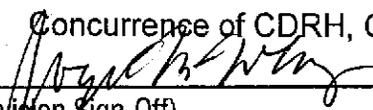
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Prescription Use  X  AND/OR Over-The-Counter Use \_\_\_\_\_ (Part 21  
CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K082228