Section 8 – 510(k) Summary

510(k) Summary

Applicant: Envisioneering, LLC
1982 Innerbelt Business Center Drive
St. Louis, MO 63114

Contact Person: David Kennedy

Telephone: 314-429-7367
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DEC 2 1 2007

Date Prepared: November 26, 2007

Trade Name: TargetScan® Biopsy kit
TargetScan® Biopsy Needle Guide

Common Name: Biopsy kit
Biopsy Needle Guide

Establishment Registration Number: 3005673110

Establishment Address: Envisioneering, LLC
1982 Innerbelt Business Center Drive
St. Louis, MO 63114

Classification of the Device: The Biopsy Kit is classified as a Biopsy Instrument, as defined in CFR 876.1075, Class II device. The Needle Guide is a Class II, CFR 892.1570

Product Code: Biopsy Kit FCG
Needle Guide ITX

Identification of Predicate Device(s):
Envisioneering TargetScan® Biopsy Kit 510(k) # K041638, originally cleared September 2, 2004.
Envisioneering TargetScan® Biopsy Needle Guide 510(k) # K041637, originally cleared September 1, 2004.

Device Description:
The sterile TargetScan® biopsy kit and Guide are designed to be used with the TargetScan® Transrectal Ultrasound system. This kit (K041638) includes The Biopsy Needle and the needle guide (K041637) containing a curved needle path which is positioned along the shaft of the probe and is held in place by a biopsy attachment. The biopsy needle in this kit is specially designed to negotiate the curved needle guide.
This needle is intended to be used with the Manan Pro-Mag Automatic Biopsy System (K980226). This biopsy kit is intended for use with the TargetScan® transrectal probe Model #TS-360-P (K041639) an anesthesia administration needle and a latex probe cover that were included in the original 510(k) are now optional components of the kit and are currently not included. These items are still recommended and can be readily obtained from other sources.

Intended Use

Purpose and Function of the Device

This device is indicated for performing planned and targeted ultrasound guided transrectal biopsies of the prostate when used with the Envisioneering TargetScan® Ultrasound system.

Intended Patient Population

This system is intended to be used with adult patients.

Intended Environment of Use

This system is intended for use by medical professionals in a physician office or hospital environment.

Technological Characteristics compared to those of the Predicate Devices

The components in the Biopsy kit are provided sterile, as are the predicate device. Minor changes to the labeling layout and package dimensions were made. An alternate contract manufacturing and sterilization facility is being added to manufacture the kits for Envisioneering Medical. The materials and intended use remain unchanged from the original 510(k). The new manufacturing facility is an FDA registered facility and the quality management system is certified to ISO 13485.

The predicate device included a 1 year shelf life; this has been tested and extended to 3 years in the modified device.

The anesthesia needle and latex probe cover included in the original 510(k) are optional components that may not be included in the kits (Currently are not included). These items are readily available from other sources and are still recommended for use.

The End of the Needle Guide has a slightly different profile than the predicate device to aid insertion into the rectum.

The Modified TargetScan® Biopsy Kit and Guide use the same basic design, same sterility assurance level (SAL 10^{-6}) and method (Ethylene Oxide), the same scientific technology and has the same intended use as the originally cleared predicate devices.

Performance Data

Applicable testing was performed in accordance with approved Validation protocols and the Risk Analysis to ensure the product is properly manufactured, packaged and sterilized. The package and materials used meet the requirements of ISO 11607-1.

Conclusion:

The addition of an alternate manufacturing and sterilization facility does not change the fundamental scientific technology or the intended use of the device as compared to the predicate device. These modifications do not raise new questions regarding safety or effectiveness of the devices originally cleared on September 1, 2004 and September 2, 2004 under 510(k) K041637 and K041638 respectively.
The performance data and declaration of conformity with design controls support the determination of continuing substantial equivalence of the previously cleared and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2007

Mr. David Kennedy
Director, Quality Assurance and Regulatory Affairs
Envisioneering Medical Technologies
1982 Innerbelt Business Center Drive
ST LOUIS MO 63114

Re: K073399
Trade/Device Name: TargetScan® Biopsy Needle Kit
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG and ITX
Dated: November 26, 2007
Received: December 4, 2007

Dear Mr. Kennedy:

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

Attachment III

Indications for Use Statement

Biopsy Needle Kit

Originally cleared under K041638

510(k) Number K073399

Device Name *TargetScan Biopsy Needle Kit*

Indications for Use

The *TargetScan Biopsy Kit* intended use is for performing planned and targeted ultrasound guided transrectal biopsies of the prostate when used with the Envisioneering TargetScan Ultrasound/ system.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073399