K041638

SEP - 2 2004

Section 3

510(k) Summary

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

Contact Person: Tom Kappel
Telephone: 314-429-7367
FAX: 314-429-7701

2. **Date Prepared:** March 22, 2004

3. **Trade Name:** TargetScan™ Biopsy kit

4. **Common Name:** Biopsy kit

5. **Establishment Registration Number:** pending

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

7. **Classification of the Device:** This device is classified as a Biopsy Instrument, as defined in CFR 876.1075, a Class II device.

8. **Identification of Predicate Device(s):**

- Manan Biopsy needle (Medical Device Technology K980122)
- EP Deflectable Catheter, (EP Medsystems K033963)

9. **Device Description:**

The sterile TargetScan™ biopsy kit is designed to be used with the Targetscan™ Transrectal Ultrasound system. This kit includes a needle guide containing a curved needle path which is positioned along the shaft of the probe and is held in place by a biopsy attachment. This needle guide is the subject of a separate submission. 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, which is the subject of a separate submission.

An anesthesia administration needle which can negotiate the curved needle guide and a latex probe cover are included in the kit as well.

10. 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.

11. Technological Characteristics compared to those of the Predicate Devices

The components in the Biopsy kit are provided sterile, as are the various predicates.

The subject and predicate device (biopsy needle) are both intended to perform biopsies of the prostate gland. They are both intended to be used with the same reusable biopsy gun. The predicate device is manufactured of a stainless steel stylet and cannula. The subject device has a nitinol stylet and a polyolefin cannula. The use of this design and these materials allows the biopsy needle to negotiate the curved biopsy guide required to take the biopsy. The performance of these devices is equivalent in bench testing.

The predicate catheter is manufactured using the same polyolefin material as the cannula of the subject device.

12. Non-Clinical Performance Data

The Biopsy needle advances 22mm during actuation of both the predicate and subject device. The needle is designed to allow the tip to protrude up to 2cm from the biopsy guide prior to firing the biopsy gun. Therefore the needle can be advanced as much 42mm beyond the disposable guide needle exit hole.

The subject needle was tested against the predicate needle in a bench test using calves' liver. In that test, they achieved comparable sample size lengths and weights.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

Envisioneering, LLC
% Ms. Chantel Carson
Section Manager
Underwriter Laboratories, Inc.
333 Pfingsten Rd.
NORTHBROOK IL 60062, USA

Re: K041638
Trade/Device Name: TargetScan Biopsy Kit
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: 90 ITX and 78 FCG
Dated: August 19, 2004
Received: August 23, 2004

Dear Ms. Carson:

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 (21 CFR Part 807); 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.

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 the letter.

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97) you may obtain. Other general information on your responsibilities under the ACT may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K041638

Device Name: TargetScan Biopsy Kit

Indications for Use:

This device is indicated for performing planned and targeted ultrasound guided transrectal biopsies of the prostate when used with the Envisioneering TargetScan model TS-360-P probe.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041638

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)