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510(k) Summary of Safety and Effectiveness

MAR 15 2011

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

Submitter:
TransEnterix, Inc.
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Prepared: 09/27/2010

Common or Usual Name: Laparoscope, General and Plastic Surgery

Proprietary Name: SPIDER™ Standard and SPIDER™ Advanced

Classification Name: GCJ, Laparoscope, General and Plastic Surgery

Manufactured By: TransEnterix, Inc.
635 Davis Drive Suite 300
Phone: (919) 765-8400
Fax: (919) 765-8459

Predicate Device(s): TransEnterix, Inc.
K090902
SPIDER™ Standard and Advanced

Device Description: The SPIDER is a pre-sterilized, single use, disposable, laparoscopic device. These devices are EO sterilized.

Intended Use: The SPIDER™ (Single Port Instrument Delivery Extended Reach) devices are intended to establish a path of entry for laparoscopic instruments for minimally invasive abdominal surgical procedures.

Comparison with Predicate Device: The intended use of this SPIDER is identical to the predicate device, the SPIDER™ as cleared in K090902.

The technological features of the SPIDER™ are the same as the predicate. The principle of operation is the same as the predicate. The dimensions and materials used in the modified system are essentially the same as the predicate device.

Furthermore, verification and validation testing provided information sufficient to

determine that the modifications did not have an effect on safety or effectiveness and demonstrated that the device met pre-determined acceptance criteria based on performance specifications. The testing demonstrated that the modified device is substantially equivalent to the predicate device and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TransEnterix, Inc.
% Ms. Bobbi L. Hadersbeck, MS
Sr. RA and Compliance Specialist
635 Davis Drive, Suite 300
Morrisville, North Carolina 27560

MAR 15 2011

Re: K102839
Trade/Device Name: SPIDER™ Standard and Advanced
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ, GCJ
Dated: February 24, 2011
Received: February 25, 2011

Dear Ms. Hadersbeck:

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

510(k) Number (if known): K102839

Indications For Use Statement

Device Name: **SPIDER™ Standard and Advanced**

Intended Use:

The SPIDER™ (Single Port Instrument Delivery Extended Reach) devices are intended to establish a path of entry for laparoscopic instruments for minimally invasive abdominal surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102839