K102646

NOV - 3 2010

510(k) Summary

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

Date: October 13, 2010

Submitter:
TransEnterix, Inc.
635 Davis Drive Suite 300
Morrisville, NC 27560

Contact: Bobbi L. Hadersbeck, M.S.
Sr. Regulatory Affairs and Compliance Specialist

Phone: (919) 765-8400 x 8554
Fax: (919) 765-8459

Propriety Name	SPIDER ™ Surgical Instruments
Common Name	Laparoscopic instrument and accessory
Classification Name:	Endoscope and accessories
Classification:	Class II 21 CFR 876.1500
Product Code:	GCJ

Predicate Device(s):
TransEnterix, Inc.
K091697
SPIDER™ Surgical Instruments, Flex Monopolar Hook

Device Description:
The Flex Monopolar Hook is a pre-sterilized, single use, disposable, electrosurgical device. These devices are gamma sterilized.

Indications for Use:

The SPIDER™ Surgical Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction/irrigation and other manipulation of tissues and vessels during laparoscopic procedures..

Comparison of Technological Characteristics with Predicate:

The SPIDER™ Flex Monopolar Hook has the same intended use and function of the predicate device. Like the predicate, the device has the same end effecter/tip design. The devices achieve the same function using the same modes of action. The modified device and predicate device are passed through the TransEnterix cannulas (IDTs) and advanced to the surgical site in exactly in the same manner.

The devices utilize the same or similar design, dimensions, and materials of construction. The design of the modified and predicate devices, in terms of length, tip size, and flexibility are the same and achieve access to the surgical space and perform their intended functions in a similar manner. Slight differences in dimensions do not present any new issues of safety or efficacy.

Both the modified and the predicate device are provided pre-sterilized, are disposable, and are single use devices. While the predicated device was ethylene oxide sterilized, the modified device is gamma sterilized.

Any technological differences between the modified device and the predicate has been mitigated via testing. Thus the SPIDER™ Flex Monopolar does not introduce any new issues of safety or effectiveness compared to other similar laparoscopic or endoscopic surgical devices currently marketed.

Performance Data:

The SPIDER™ Flex Monopolar Hook has been functionally tested in bench top simulation studies and found to perform its intended function for laparoscopic surgical procedures. The functional testing included passing flexible instruments through the SPIDER device's instrument delivery tubes, manipulation of the instruments within the SPIDER, evaluation of instrument interference, evaluation of the instrument function i.e. ability to cauterize, etc. In addition a preclinical animal study evaluated the system performance to ensure the ability to perform the intended clinical function. The preclinical study evaluated all instruments and the SPIDER device while used together.

Biocompatibility testing was conducted in accordance with the following standards for an external communicating device in contact with tissue/bone/dentin with an exposure time of 24 hours or less:

- ISO 10993-1:2003 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
- ISO 10993-5:1999 – Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2002 and 10993-10:2002/A1:2006 – Biological Evaluation of Medical Devices- Part 10: Tests for irritation and delayed type hypersensitivity

- ISO 10993-12:2007 – Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference.

The sterilization process was validated and based on determination of bioburden. The sterilization validation confirmed that the gamma process maintained a sterility assurance level (SAL) of $1x10^{-6}$. :

- ISO11137-1:2006 – Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2007 – Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

Although sterile packaging did not change, a packaging validation was performed in accordance with the following standards to assure consistency of the packaging process. The 3 lot packaging validation was successful.

- ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes.

Lastly, in consideration of the sterilization change from EO to gamma, shelf life studies, both accelerated and real time, were conducted in accordance with ISO 11607-1 and 11607-2 and ASTM F1980-07, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices".

In addition, transit testing was conducted in accordance with the following standards:

- ASTM D 4169-05 Performance Testing of Shipping Containers and Systems.*
- ISTA Project 2A Series (2008) Partial-Simulation Performance Test Procedure Packaged Products 150lb or less.
- ASTM F 2096-04 Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).*
- ASTM F 88-09 Standard Test Method for Seal Strength of Flexible Barrier Materials.*

Electrical safety testing was performed according to related sections of the following standards:

- IEC 60601-1: Medical Electrical Equipment-part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment

These verification and validation test results are sufficient to demonstrate safety and effectiveness compared to predicate devices used in standard laparoscopic surgical techniques. Any minor technological differences in the design or materials of the SPIDER™ Surgical Instruments have been evaluated and found to present no new issues of safety and effectiveness.

Conclusion:

The conclusion drawn from the test data is that the modified SPIDER™ Flex Monopolar Hook is as safe and effective as the predicate device, perform similarly to the predicate devices for laparoscopic surgery, and does not raise any new issues of safety or effectiveness.

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, M.S.
Senior Regulatory Affairs and
Compliance Specialist
635 Davis Drive, Suite 300
Morrisville, North Carolina 27560

NOV - 3 2010

Re: K102646
Trade/Device Name: SPIDER™ Surgical Instruments, Flex Monopolar Hook
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 13, 2010
Received: October 14, 2010

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): K102646

NOV - 3 2010

Indications For Use Statement

Device Name: **SPIDER™ Surgical Instruments, Flex Monopolar Hook**

Intended Use:

The SPIDER Surgical Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction/irrigation and other manipulation of tissues and vessels during laparoscopic 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)

(Division Sign-Off) (Optional Format 1-2-96)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102646