

510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April 11, 2012

1. Submitter:

Submitted by: **TransEnterix, Inc.**
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Contact: Tammy Carrea
VP Quality and Regulatory Affairs

2. Device:

Propriety Name: SPIDER® Flexible Blunt Dissector and Band Passer
Common Name: Laparoscopic instrument and accessory
Classification Name: Endoscope and accessories
Classification: Class II 21 CFR 876.1500
Product Code: GCJ

3. Predicate Devices:

Class:	510(k) Number:	Device Name/Description:
II	K100109	Logiflex Laparoscopic Band Positioning Device
I	None	Realize Blunt Dissector (previously known as the Obtech Medical Goldfinger Blunt Dissector)
II	K091697	SPIDER Flexible Grasper

4. Description:

The SPIDER® Flexible Blunt Dissector and Band Passer device is a surgical instrument used to facilitate laparoscopic surgery. It is intended for use with the SPIDER® Single Port Device or other laparoscopic access device that facilitates the use of rigid and/or flexible instrumentation.

The SPIDER® Flexible Blunt Dissector and Band Passer instrument has a flexible shaft with an articulating distal tip. The distal tip is blunt to allow tissue dissection between tissue layers and the articulation is actuated via a proximal ratcheted handle. The blunt

tip includes a shallow slot to grab sutures as applicable. It also includes a non-electrical retractable loop (grasping loop) for grasping and pulling tubing, sutures, or tissue. The instrument is provided sterile and is a single use, disposable device.

5. Indications for Use:

The SPIDER® Flexible Blunt Dissector and Band Passer is indicated for use with the SPIDER® single port device (SPIDER® Surgical Platform) during laparoscopic surgery to dissect tissue layers, to pull tubing and to generally assist in the placement of gastric bands.

6. Comparison of Technological Characteristics with Predicate:

The SPIDER® Flexible Blunt Dissector and Band Passer device utilizes the same or similar design, dimensions, materials of construction, and sterilization as that of the SPIDER Flexible Grasper. The flexible design and length of the SPIDER® Flexible Blunt Dissector and Band Passer device is essentially the same as the SPIDER® Flexible Grasper currently marketed.

Similar to the predicate devices the SPIDER® Flexible Blunt Dissector and Band Passer device is provided pre-sterilized, is disposable, and is a single use device, the same as other predicate devices.

The SPIDER® Blunt Dissector and Band Passer device has a blunt tip to facilitate tissue dissection and an articulating distal tip similar to the gastric band predicate devices. All of the devices include a slot to capture and pull a suture. The only technological difference in the SPIDER® Flexible Blunt Dissector and Band Passer device and the gastric band predicate devices is the mechanical mechanism for grabbing and pulling a band. The Logiflex Band Positioning Device and the Realize Blunt Dissector (Goldfinger) use a large open slot to capture the band. The SPIDER® Flexible Blunt Dissector and Band Passer device uses a retractable mechanical loop that can be deployed to grab and pull bands. This technological feature has been tested in simulated use bench studies and in a cadaver model to demonstrate that it fulfills its intended use with regard to grabbing and pulling bands.

Any technological differences between the SPIDER® Flexible Blunt Dissector and Band Passer device and the predicates have been mitigated via functional, simulated use, and preclinical testing. Thus the SPIDER® Flexible Blunt Dissector and Band Passer device does not introduce any new issues of safety or effectiveness compared to other similar laparoscopic or endoscopic surgical devices currently marketed.

7. Performance Data:

Functional testing of the SPIDER® Flexible Blunt Dissector and Band Passer device was conducted during bench studies to evaluate the articulation angle, strength, function of the blunt tip, function of loop, cycle testing for reliability, and was tested under simulated use conditions. The simulated use testing was conducted by testing the instrument with the SPIDER® laparoscopic device and tissue samples (chicken tissue). The study found

that the SPIDER® Flexible Blunt Dissector and Band Passer device performed as intended and remained functional following cycle testing.

Gamma sterility testing has been conducted for the SPIDER® Flexible Instruments Family which includes the Blunt Dissector and Band Passer device and has been shown to achieve a sterility assurance level of 1×10^{-6} . In addition the sterile barrier packaging has been tested for the Flexible Instruments family and has been found to maintain sterility during shelf life testing.

The SPIDER® Flexible Blunt Dissector and Band Passer device has been tested for biocompatibility in accordance with ISO 10993-1 based on the duration of contact and type of contact. The studies concluded that the instruments are non-toxic, non-irritating, and non-sensitizing.

Pre-clinical testing in a cadaver model study was performed and demonstrated that the SPIDER® Flexible Blunt Dissector and Band Passer device compares to that of standard laparoscopic instruments and predicate devices in terms of performing blunt dissection and band positioning in laparoscopic procedures.

8. Conclusion:

The conclusion drawn from the test data is that the SPIDER® Flexible Blunt Dissector and Band Passer is as safe and effective as the predicate devices, has the same intended use and performs similarly to other legally marketed 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.
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VP Quality and Regulatory Affairs
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Durham, North Carolina 27713

APR 16 2012

Re: K120403
Trade/Device Name: SPIDER® (Single Port Instrument Delivery Extended Reach) Blunt
Dissector and Band Passer device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 8, 2012
Received: February 9, 2012

Dear Ms. Carrea:

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

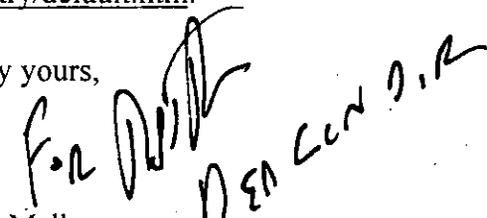
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (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" (21 CFR 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) No. K120403

If known

Indications For Use Statement

Device Name: **SPIDER® (Single Port Instrument Delivery Extended Reach) Blunt Dissector and Band Passer device**

Indications For Use:

The SPIDER® Flexible Blunt Dissector and Band Passer is indicated for use with the SPIDER® single port device (SPIDER® Surgical Platform) during laparoscopic surgery to dissect tissue layers, to pull tubing and to generally assist in the placement of gastric bands.

Prescription Use
 (Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thif RPD glem for max
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K12 0403