K101671



## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN 25 2010

### Single-Site™ Flexible Bladeless Obturator

**A. Name, Address, Phone and Fax Number of Applicant**

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-4904
Fax: 919-433-4996

**B. Contact Person**

Angela Bouse
Sr. Regulatory Affairs Specialist

**C. Date Prepared**

June 11, 2010

**D. Device Name**

Trade Name: Single-Site™ Flexible Bladeless Obturator

Common Name: Surgical Trocar

Classification Name: Endoscope and Accessories (21 CFR 876.1500, Product Code GCJ)

**E. Device Description**

The Single-Site™ Flexible Bladeless Obturator is a sterile, single-use 5mm diameter X 304 mm length dilating obturator that is used in conjunction with a 5mm Curved Cannula. The Obturator has a cap at the proximal end that locks onto the Curved Cannula rim. The Curved Cannula is designed by Intuitive Surgical, Inc. (ISI) for use with their DaVinci SI robot model.

**F. Indications for Use**

The Single-Site™ Flexible Bladeless Obturator is indicated for use in thoracic, abdominal, and gynecologic minimally invasive surgical procedures to provide a pathway for the introduction of endoscopic surgical devices.

## G. Contraindications

Where minimally invasive techniques are contraindicated, other methods and instrumentation should be employed.

## H. Substantial Equivalence

The proposed Single-Site™ Flexible Bladeless Obturator is substantially equivalent to the predicate device:

| Predicate Device | Manufacturer | 510(k) No. | Date Cleared |
|---|---|---|---|
| The ADAPt™ Laparoscopic Port and Accessory | Teleflex Medical, Inc. / Taut, Inc. | K010007 | 02/22/2001 |

## I. Comparison To Predicate Device

The tip design and function of the proposed Single-Site™ Flexible Bladeless Obturator is identical to the predicate device's Obturator component except that the Single-Site™ Flexible Bladeless Obturator has the following changes:

- 304mm obturator length;
- The Tip Length is longer, this insures a smooth transition area between the distal cannula end and the obturator tip. The Tip Length is described as the section of the obturator tip that protrudes from the cannula after the obturator is inserted into the cannula;
- The Obturator Cap designed to lock and unlock from the Curved Cannula rim to support obturator / cannula assembly;
- IFU revision for clarity to insure proper use of the Obturator with the Curved Cannula.

## J. Materials

All materials that have patient contact have been cleared in predicate device under 510(k) K010007. There are no new patient contact materials used in Single-Site™ Flexible Bladeless Obturator.

## K. Performance Data

Verification testing was performed to demonstrate that the proposed Single-Site™ Flexible Bladeless Obturator is inserted and removed from the Curved Cannula without any evidence of material degradation.

**L. Conclusion**

The test results demonstrate the proposed Single-Site™ Flexible Bladeless Obturator is compatible with the ISI Curved Cannula. The changes made to the proposed Single-Site™ Flexible Bladeless Obturator do not introduce any new issues of safety and 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

JUN 25 2010

Teleflex Medical, Inc.
% Ms. Angela Bouse
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K101671
Trade/Device Name: Single-Site™ Flexible Bladeless Obturator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 11, 2010
Received: June 14, 2010

Dear Ms. Bouse:

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

# Indications for Use



**510(k) Number:** K101671

**Device Name:** Single-Site™ Flexible Bladeless Obturator

**Indications for Use:**

The Single-Site™ Flexible Bladeless Obturator is indicated for use in thoracic, abdominal, and gynecologic minimally invasive surgical procedures to provide a pathway for the introduction of endoscopic surgical devices.

**Prescription Use XX**
(Part 21 CFR 801 Subpart D)

AND/OR

**Over-the-counter use __**
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101671