SEP 1 0 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K082156

The ADAPt™ Universal Laparoscopic Port

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
Regulatory Affairs Specialis

C. Date Prepared

July 29, 2008

D. Device Name

Trade Name: The ADAPt™ Universal Laparoscopic Port

Common Name: Surgical Trocar

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

E. Device Description

The ADAPt™ Universal Laparoscopic Port consists of an obturator and cannula set which will accommodate instruments in the 5-10mm range with a cannula length of 100mm and the 5-10-12mm range with cannula lengths of 100mm and 125mm. The device utilizes a set of three seals. The first seal is the Floating Top Seal which accommodates instruments ranging from 10mm to 12mm. The second seal is the Floating Caged Seal which accommodates instruments in the 5mm range. The third seal is the Duck Bill Seal used to maintain insufflation, if no instruments are placed in the port during surgery.

F. Indications for Use

The ADAPt™ Universal Laparoscopic Port 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 ADAPt™ Universal Laparoscopic Port 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 basic design and function of the proposed ADAPt™ Universal Laparoscopic Port is identical to the predicate device, except that the ADAPt™ Universal Laparoscopic Port has the following changes:

- Includes a Floating Caged Seal which is composed of two rigid halves made of valox providing the structural integrity of the seal, the valox core is overmolded all around the outer edges with the silicone which provides sealing capability of the seal. The two halves are held in place with an elastic hinge on one side and secured by a pair of magnets on the other side;
- A Rotary Valve Chamber was created to accommodate the Floating Caged Seal;
- The shaft of the obturator is lengthened to accommodate the extended height of the Rotary Valve Chamber.

J. Materials

All materials that have patient contact, for exception of Valox core overmolded with CLS 8110 Silicone Parylene N Cating 1.0-1.8 uM thick, have been cleared in predicate device under 510(k) K010007. New material was tested in accordance with ISO 10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed ADAPt™ Universal Laparoscopic Port and the predicate device has been performed. The results of this comparison demonstrate that the ADAPt™ Universal Laparoscopic Port is equivalent to the marketed predicate devices in performance characteristics.

L. Performance Data

The bench testing has been performed to verify that the performance of the proposed ADAPt™ Universal Laparoscopic Port is substantially equivalent to the predicate device, and that the ADAPt™ Universal Laparoscopic Port will perform as intended.

M. Conclusion

Based upon the comparative test results, the proposed ADAPt™ Universal Laparoscopic Port is substantially equivalent in performance to the predicate device cleared to market via 510(k) K010007. The changes made to the proposed ADAPt™ Universal Laparoscopic Port do not introduce any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2008

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

Re: K082156
Trade/Device Name: ADAPt™ Universal Laparoscopic Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 25, 2008
Received: August 26, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082156

Device Name: ADAPt™ Universal Laparoscopic Port

Indications for Use:

The ADAPt™ Universal Laparoscopic Port 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) **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 General, Restorative, and Neurological Devices

510(k) Number K082156