K081169

510(k) Summary of Safety and Effectiveness

SUBMITTER:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien) 60 Middletown Avenue North Haven, CT 06473 USA
	MAY 23 2008
CONTACT PERSON:	Tim M. Lohnes, Manager, Regulatory Affairs
DATE PREPARED:	April 28, 2008
TRADE/PROPRIETARY NAME:	autosuture™ VERSAPORT™ PLUS Bladeless Trocar
COMMON/USUAL NAME:	Surgical Trocar
CLASSIFICATION NAME:	Endoscope and Accessories
PREDICATE DEVICE(S):	autosuture™ VERSAPORT, Ethicon Excel™
DEVICE DESCRIPTION:	The autosuture™ VERSAPORT™ PLUS Bladeless trocar is available in diameters from 5mm to 15mm, including short, standard and long length cannula. The 5mm VERSAPORT™ fixed seal system accommodates 5mm instruments, while the VERSAPORT™ PLUS removable seal systems accommodate instruments ranging from 5 mm to 15 mm (the 10/15mm system includes a converter for 5 mm diameter instruments). There is a stopcock valve for insufflation and rapid desufflation.
INTENDED USE:	The autosuture™ VERSAPORT™ PLUS Bladeless trocar is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.
TECHNICAL CHARACTERISTICS:	The autosuture™ VERSAPORT™ PLUS Bladeless trocar with and/or without fixation sleeve is equivalent to the predicate devices in terms of its intended use. The autosuture™ VERSAPORT™ PLUS Bladeless trocar obturator has 2 linear non-bladed fins, a non-bladed rounded pin tip, and a spring-loaded shield. The trocar sleeve housing contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The device will be offered with and/or without a fixation sleeve.
MATERIALS:	All components of the autosuture™ VERSAPORT™ PLUS Bladeless trocar are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	In-vitro and in-vivo tests were performed to verify that the performance of the autosuture™ VERSAPORT™ PLUS Bladeless trocar is substantially equivalent to the predicate devices, and to validate that the autosuture™ VERSAPORT™ PLUS Bladeless trocar will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Covidien LP
% Mr. Tim M. Lohnes
Manager, Regultory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K081169
Trade/Device Name: autosuture™ Bladeless VERSAPORT™ PLUS trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 21, 2008
Received: April 24, 2008

Dear Mr. Lohnes:

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

510(k) Number (if known): K081169

Device Name:

autosuture™ Bladeless VERSAPORT™ PLUS trocar

Indications For Use:

The autosuture™ VERSAPORT™ PLUS Bladeless Trocar is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative and Neurological Devices