7. 510(K) SUMMARY:

FEB 2 4 2011

510(k) Summary of Safety and Effectiveness:

SUBMITTER:	Covidien (formerly registered as US Surgical, a division of Tyco Healthcare) 60 Middletown Avenue North Haven, CT 06473
CONTACT PERSON:	Tim M. Lohnes Manager, Regulatory Affairs Phone: (203) 492-5462 Fax: (203) 492-5029 tim.lohnes@covidien.com alternate contact: sharon.murphy@covidien.com
DATE PREPARED:	November 02, 2010
TRADE/PROPRIETARY NAME:	SILS™ Port
COMMON/USUAL NAME:	Surgical Trocar
CLASSIFICATION NAME:	Endoscope and/or accessories
PREDICATE DEVICE(S):	K000180: Richard Wolf Medical Instrument Corp. Transanal Endoscopic Microsurgery (TEM) Combination System and Instrument Set K093372: Covidien SILS™ Port
DEVICE DESCRIPTION:	Three laparoscopic trocars and an insufflation tube bound by a flexible port.
INTENDED USE:	For multiple instrument or camera access to the abdominal cavity through a single incision for performing minimally invasive laparoscopic procedures, as well as through the anus to provide access for rectal procedures such as TEMS (Transanal Endoscopic Micro Surgery), flap revision and fistula repair.

Covidien (formerly registered as US Surgical a division of Tyco Healthcare).

TECHNOLOGICAL CHARACTERISTICS:	The SILS™ Port allows the use of three laparoscopic cannula and an insufflation port in a body cavity through a single incision or to the rectum via the anus (no incision).
MATERIALS:	All components of the SILS™ Port are comprised of materials that have been evaluated in accordance with ISO 10993-1: 2009, Biological Evaluation of medical devices -- Part 1: Evaluation and Testing.
PERFORMANCE DATA:	In-vivo and in vitro evaluations were performed to support the use of the SILS™ Port device for transanal access for rectal surgery. The testing included in vitro suture pull out testing as well as in vivo (porcine) transanal evaluations including insertion force, port security, visualization, removal force, and resultant trauma. The results of this testing indicate that when used for transanal access for rectal surgery, SILS™ Port is safe and effective and provides equivalent performance to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Tim M. Lohnes
RA Manager
Covidien
60 Middletown Avenue
NORTH HAVEN CT 06473

FEB 24 2011

Re: K103253
Trade/Device Name: SILS™ Port
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ and FER
Dated: November 2, 2010
Received: November 30, 2010

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. 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. INDICATIONS FOR USE STATEMENT:

510(k) Number (if known): K103253

Device Name: SILS™ Port

Indications For Use:

The SILS™ Port device is indicated for multiple instrument or camera access to the abdominal cavity through a single incision for performing minimally invasive laparoscopic procedures, as well as through the anus to provide access for rectal procedures such as TEMS (Transanal Endoscopic Micro Surgery), flap revision and fistula repair.

Prescription Use: _____X_____ OR Over-The-Counter Use:_____
(Per 21 CFR 801.109)

(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 Reproductive, Gastro-Renal, and Urological Devices
(510k) Number K103253

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