5. 510(K) SUMMARY:

510(k) Summary of Safety and Effectiveness: SEP - 1 2009

SUBMITTER: Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien)
60 Middletown Avenue
North Haven, CT 06473

CONTACT PERSON: Robert Zott
Program Director, Regulatory Affairs
Phone: (203) 492-6013
Fax: (203) 492-5029

DATE PREPARED: Revised August 13, 2009

TRADE/PROPRIETARY NAME: SILS™ Clincher* / SILS™ Dissector*
SILS™ Grasper* / SILS™ L-Hook*
SILS™ Shears*

COMMON/USUAL NAME: Endoscopic Hand Instruments

CLASSIFICATION NAME: Endoscopic Hand Instruments

PREDICATE DEVICE(S):
K951589: Auto Suture™ Modified Endoscopic Hand Instruments
K914753: Auto Suture™ Articulating Endoscopic Clamp
K914752: Auto Suture™ Articulating Endoscopic Scissors
K905426: Auto Suture™ Modified Endo Stream Suction/Irrigation Device
K904578: Auto Suture™ Modified Endoscopic Clamp

PRIOR RELATED SUBMISSION(S):

For Single Incision Procedures:
K090419: SILS™ Stitch Endoscopic Suturing Device
K082619: SILS™ Port Multiple Instrument Access Port
K072814: Convenience Kit for "Single-Incision Laparoscopic Surgery and other advanced laparoscopic procedures."

*Specific trade names to be determined.
Revised August 31, 2009

All predicate devices including those cleared in the prior related submissions are manufactured by Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien)

DEVICE DESCRIPTION:

Each single use SILS™ Hand Instrument contains a pistol grip, a rigid shaft with an articulating and rotating end effector, and opposing jaws or an electrocautery hook at the distal end.

INDICATIONS:

The SILS™ Clincher* single use articulating clincher has application in a variety of endoscopic, gynecological, and general laparoscopic procedures for temporarily clamping or grasping tissues and small tubular structures.

The SILS™ Dissector* single use articulating dissector with monopolar cautery has application in a variety of endoscopic, gynecological, and general laparoscopic procedures to temporarily grasp or clamp tissues and small vessels or body structures, and for use in blunt dissection. When connected to an electrosurgical power source, the device may be used to apply monopolar cautery in accordance with the recommendations of the electrosurgical unit's manufacturer.

The SILS™ Grasper* single use articulating grasper has application in a variety of endoscopic, gynecological, and general laparoscopic procedures to temporarily grasp or clamp tissues and small vessels or body structures, and for use in blunt dissection.

The SILS™ L-Hook* single use articulating hook with monopolar cautery has application in endoscopic, gynecological, and general abdominal and thoracic laparoscopic procedures. When connected by a standard cable to an electrosurgical power source, the device may be utilized for monopolar cautery.

The SILS™ Shears* single use articulating shears with monopolar cautery has application in a variety of endoscopic, gynecologic, and general laparoscopic procedures for transection and cutting of tissues. When connected to an electrosurgical power source, the device may be used to apply monopolar cautery in accordance with the recommendations of the electrosurgical unit's manufacturer.

*Specific trade names to be determined.
Revised August 31, 2009

TECHNOLOGICAL CHARACTERISTICS:	The clincher, dissector, grasper, and shears contain opposing jaws to manipulate tissue, and the dissector, L-hook, and shears administer electrocautery. The end effector of each instrument articulates when the handle is deflected relative to the shaft and rotates when a rotation wheel is turned.
MATERIALS:	All patient contact materials in the SILS™ Hand Instruments have been evaluated in accordance with ISO 10993-1: 2003, Biological Evaluation of medical devices -- Part 1: Evaluation and Testing.
PERFORMANCE DATA:	In-vitro and in-vivo testing has been performed in support of the intended use of these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP - 1 2009

Covidien LP
% Mr. Robert Zott
Program Director, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06511

Re: K091869
Trade/Device Name: SILS™ Clincher*, SILS™ Dissector*, SILS™ Grasper*, SILS™ L-Hook*, SILS™ Shears*
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 13, 2009
Received: August 14, 2009

Dear Mr. Zott:

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 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.

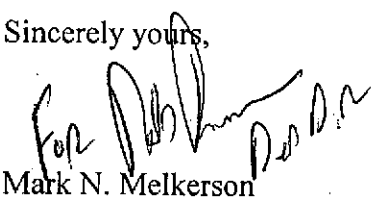
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/mdr/ 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 (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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091869

Indications for Use

510(k) Number (if known): K091869

Device Name: SILS™ Clincher*, SILS™ Dissector*, SILS™ Grasper*, SILS™ L-Hook*, SILS™ Shears*

Indications For Use:

The SILS™ Clincher* single use articulating clincher has application in a variety of endoscopic, gynecological, and general laparoscopic procedures for temporarily clamping or grasping tissues and small tubular structures.

The SILS™ Dissector* single use articulating dissector with monopolar cautery has application in a variety of endoscopic, gynecological, and general laparoscopic procedures to temporarily grasp or clamp tissues and small vessels or body structures, and for use in blunt dissection. When connected to an electrosurgical power source, the device may be used to apply monopolar cautery in accordance with the recommendations of the electrosurgical unit's manufacturer.

The SILS™ Grasper* single use articulating grasper has application in a variety of endoscopic, gynecological, and general laparoscopic procedures to temporarily grasp or clamp tissues and small vessels or body structures, and for use in blunt dissection.

The SILS™ L-Hook* single use articulating hook with monopolar cautery has application in endoscopic, gynecological, and general abdominal and thoracic laparoscopic procedures. When connected by a standard cable to an electrosurgical power source, the device may be utilized for monopolar cautery.

The SILS™ Shears* single use articulating shears with monopolar cautery has application in a variety of endoscopic, gynecologic, and general laparoscopic procedures for transection and cutting of tissues. When connected to an electrosurgical power source, the device may be used to apply monopolar cautery in accordance with the recommendations of the electrosurgical unit's manufacturer.

* Specific trade names to be determined.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K091869