5. 510(K) SUMMARY:

APR 16 2008

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
CONTACT PERSON:	Robert Zott Program Director, Regulatory Affairs Phone: (203) 492-6013 Fax: (203) 492-5029
DATE PREPARED:	September 21, 2007
TRADE/PROPRIETARY NAME:	To Be Determined
COMMON/USUAL NAME:	Convenience Kit
CLASSIFICATION NAME:	Convenience Kit
PREDICATE DEVICE(S):	K883018: Endo Clip* 5mm Clip Applier K914753: Roticulator Endo Dissect* 5mm, Endo Grasp* 5mm, & Endo Mini-Shears* 5mm K920599: AcuClip* Right Angle Clip Applier K922123: Endo Catch* Gold K951589: Roticulator Endo Sciz* 5mm Hook Scissors K981941: Dexide* 5mm Threaded Trocar K012539: VersaStep* Plus 12mm Trocar All predicate devices manufactured by Surgical Devices, a global business of Tyco Healthcare Group LP (d/b/a/ Covidien)

Surgical Devices, a global business unit of Tyco Healthcare Group, LP (d/b/a Covidien)

DEVICE DESCRIPTION:	Convenience kit of laparoscopic instruments.
INTENDED USE:	"Single-Incision Laparoscopic Surgery and other advanced laparoscopic procedures."
TECHNOLOGICAL CHARACTERISTICS:	The convenience kit contains various configurations of tools for the performance of laparoscopic procedures. These tools provide laparoscopic access, tissue dissection and manipulation, hemostasis, and specimen collection.
MATERIALS:	Unchanged from predicate devices.
PERFORMANCE DATA:	Relevant clinical literature has been cited in support of the intended use of this convenience kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2008

Covidien
% Mr. Robert Zott
Program Director, Regulatory
Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K072814
Trade/Device Name: Convenience Kit for "Single-Incision Laparoscopic Surgery and and other advanced laparoscopic procedures."
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 20, 2008
Received: March 21, 2008

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 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

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Attachment 1

Indications for Use

510(k) Number (if known):	K072814
Device Name:	Convenience Kit for "Single-Incision Laparoscopic Surgery and other advanced laparoscopic procedures."
Indications for Use:	For Single-Incision Laparoscopic Surgery and other advanced laparoscopic procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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.C. Ogden for MXM

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

510(k) Number K072814