510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien (formerly registered as Tyco Healthcare, LP) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5000
CONTACT PERSON:	Joseph Canavan Senior Design Quality Engineer Covidien Phone: (203) 492-8032 Fax: (203) 492-5029
DATE PREPARED:	January 6, 2012
TRADE/PROPRIETARY NAME:	Wound Protector
COMMON/USUAL NAME:	Sterile Surgical Drape
CLASSIFICATION NAME:	Surgical Drape and Drape Accessories per 21 CFR 878.4370
PREDICATE DEVICE:	Applied Medical, Alexis™ Wound Retractors (K041711)
DEVICE DESCRIPTION:	Wound retraction device providing access and protection from wound contamination.
INTENDED USE:	The Wound Protector is indicated for use to access the abdominal cavity during surgery through an atraumatically retracted incision, deliver maximum exposure of the abdominal cavity with minimum incision size, and protect against wound contamination during laparoscopic and open surgery. Additionally, the small size Wound Protector is indicated for use to access the thoracic cavity during cardiac and general surgical procedures through an atraumatically-retracted incision.
TECHNOLOGICAL CHARACTERISTCS:	The Wound Protector Cylindrical Film is designed to retract an incision and provide protection from wound contamination. The Interior and Exterior rings are flexible to aid insertion, film retraction, and removal.
MATERIALS:	All patient-contacting components of the Wound Protector 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-vitro and in-vivo testing to support the intended use of this device includes: o Film Penetration (Tear) Resistance (ASTM D3787) o Strength of Attachment between Film and Exterior Ring (Tensile/Elongation) o Strength of Attachment between Film and Interior Ring (Tensile/Elongation) o Film Weld Seam Strength (ASTM D412) o Ease of Digital Insertion

- Incision Retraction / Rolling
- Ease of Use
- Instrument Access / Specimen Removal
- Specimen Manipulation
- Ease of Removal
- Film Tear Resistance In-Vivo
- Tissue Trauma

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Covidien LLC
% Mr. Joseph Canavan
Senior Design Quality Engineer
60 Middleton Avenue
North Haven, Connecticut 06472

MAR 27 2012

Re: K120061
Trade/Device Name: Wound Protector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCI, KKX
Dated: January 6, 2012
Received: January 9, 2012

Dear Mr. Canavan:

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,

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

Enclosure

K120061

Indications for Use

510(k) Number (if known):

Device Name: Wound Protector

Indications for Use:

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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)

Mark P Ogden for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120061