

K100242

**510(k) Summary of Safety and Effectiveness**

FEB 17 2010

**SUBMITTER:** Surgical Devices, a global business unit  
of Tyco Healthcare Group LP (d/b/a Covidien)  
60 Middletown Avenue  
North Haven, CT - 06473  
Tel. No.: (203) 492-6339

**CONTACT PERSON:** Nishith Desai  
Associate Manager, Regulatory Affairs

**DATE PREPARED:** January 20, 2010

**TRADE/PROPRIETARY NAME:** Auto Suture™ ENDO CLIP™ III 5mm Clip Applier

**COMMON/USUAL NAME:** Implantable Clip

**CLASSIFICATION NAME:** Implantable Clip

**PREDICATE DEVICE(S):** Auto Suture™ ENDO CLIP™ III 5mm Clip Applier (K071406, K061288) and Auto Suture™ ENDO CLIP™ Disposable Clip Applier (K883018)

**DEVICE DESCRIPTION:** The Auto Suture™ ENDO CLIP™ III 5mm Clip Applier contains 16 titanium clips. The applier is designed for introduction and use through an appropriately sized trocar sleeve, or larger with the use of a converter. The ENDO CLIP™ III 5mm Clip Applier consists of a trigger handle, shaft rotation knob, clip counter window and a 33 cm shaft with jaws at its distal end. Squeezing the handle places a titanium clip in the jaws and closes the jaws to close the clip on the vessel or structure.

**INTENDED USE:** The Auto Suture™ ENDO CLIP™ III 5mm Clip Applier is primarily indicated for patients undergoing laparoscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures, and for radiographic marking.

**TECHNOLOGICAL CHARACTERISTICS:** The Auto Suture™ ENDO CLIP™ III 5mm Clip Applier is identical to the predicate device in terms of intended use and it operates in a similar manner as the predicate device.

**MATERIALS:** All patient contact components of the Auto Suture™ ENDO CLIP™ III 5mm Clip Applier 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 ENDO CLIP™ III 5mm Clip Applier was substantially equivalent to the predicate devices in occluding vessels and other tubular structures and to validate that the ENDO CLIP™ III 5mm Clip Applier performed as intended.



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

Surgical Devices, a division of  
Tyco Healthcare Group LP  
% Nishith Desai  
60 Middletown Avenue  
North Haven, Connecticut 06473

FEB 17 2010

Re: K100242

Trade/Device Name: Auto Suture™ ENDO CLIP™ III 5mm Clip Applier  
Regulation Number: 21 CFR 878.4300  
Regulation Name: Implantable clip  
Regulatory Class: II  
Product Code: FZP, GDO  
Dated: January 26, 2010  
Received: January 27, 2010

Dear Nishith Desai:

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.

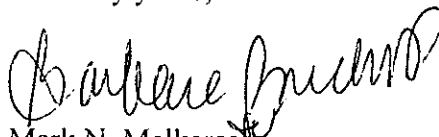
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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

## Indications For Use

510(k) Number (if known): K100242

Device Name: Auto Suture™ ENDO CLIP™ III 5mm Clip Applier

Indications For Use:

The Auto Suture™ ENDO CLIP™ III 5mm Clip Applier is primarily indicated for patients undergoing laproscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures, and for radiographic marking.

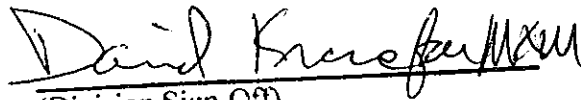
Prescription Use X  
(Part 21 CFR 801 Subpart D)

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)



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K100242