K121600

page 1/3

510(k) Summary

JUL 16 2012

Company Ethicon Endo-Surgery, LLC
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Guaynabo, PR 00969

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Date Prepared May 31, 2012

Device Name
Trade Name: Echelon Endoscopic Linear Cutter Reload, White
Common or Usual Name: Endoscopic and Accessory
Classification Name: Staple, Implantable

Predicate Devices
Echelon Endoscopic Linear Cutter Reload, White (K081146, K070887, K051002)
Echelon Endoscopic Linear Cutter Reload, Black (K112056)

Device Description
The Echelon Endoscopic Linear Cutter Reload, White, is a thin tissue reload for use with the Echelon Endoscopic Linear Cutter devices (Echelon, Echelon Flex, Echelon Powered Flex) in a 60mm configuration. It is part of the current Echelon reload family and will provide a closed staple height of 1.0 mm for use in thin tissue such as mesentery and pulmonary and renal artery and vessels.

Indications for Use
The ECHELON families of endoscopic linear cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Technological Characteristics

The design and performance of the subject device is based on the currently marketed Echelon white reload. In addition a pocket extension feature has been added to the subject device. This feature was introduced in K112056 for the Echelon Black reload submission. MR compatibility data has been derived from the testing performed for the Echelon Black reload. The data for the Black reload represents the worst case scenario, due to its larger staple design and greater mass.

Performance Data

Bench and Animal testing was performed to demonstrate that the device updates do not affect safety and effectiveness and that the device will perform as intended.

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

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Incorporated
Ms. Asifa Vonhof, RAC
Regulatory Affairs Associate II
4545 Creek Road
Cincinnati, Ohio 45242

JUL 16 2012

Re: K121600
Trade/Device Name: Echelon Endoscopic Linear Cutter Reload, White
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: May 31, 2012
Received: June 01, 2012

Dear Ms. Vonhof:

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,

for 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): K121600

Device Name: Echelon Endoscopic Linear Cutter Reload, White

Indications for Use:

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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)

Daniel Kanefsky MM

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

510(k) Number K121600