K100723 Page 1/6

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: October 17, 2009

APR 30 2010

1. Company and Correspondent making the submission:

Name – Changzhou Kangdi Medical Stapler Co., Ltd.
Address – No.16, Kunlun Road, Xinbei Zone,
Changzhou Jiangsu, China 213022
Telephone – +86-519-85162780
Fax – +86-519-85139853
Contact – Fleming Jiang, Quality Manager
Email – jiangmingfang@kanghui-china.com

2. Device :

Trade/proprietary name: Disposable Circular stapler
Common Name : Implantable Staple
Classification Name : Staple, implantable

Predicate Devices:

Manufacturer	Device Name	510(k) Number
Ethicon Endo-Surgery, Inc.	Endopath ILS Endoscopic Circular Stapler 25mm, 29mm	K920752

3. Classifications Names & Citations :

   21CFR 878.4750, GDW, Implantable Staple

4. Description :

   4.1 General

   The disposable circular stapler is preloaded with two staggered rows of titanium staples in both inner and outer circles. After the deploying of the instrument, the circular knife blade inside the instrument can cut off excess tissue automatically to create a circular anastomosis. The instrument is fired by squeezing the trigger handle firmly as far as it will go. The size of the anastomosis site is determined by the diameter of the selected circular knife blade.

5. Indication for use :

   The Disposable Circular Stapler has application throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.

6. Comparison with predicate device: - Please see next page for the comparison table.

Disposable Circular Stapler Product Features Comparison Chart

Features & Description	Changzhou Kangdi Medical Stapler Co., Ltd Disposable Circular Stapler (DCS) 25.5mm, 28.5mm	Predicate Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler 25mm, 29mm
Name	Changzhou Kangdi Medical Stapler Co., Ltd Disposable Circular Stapler KYGW-25.5, KYGW-28.5	Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler 25mm, 29mm
Manufacturer of Record	Changzhou Kangdi Medical Stapler Co., Ltd	Ethicon Endo-Surgery, Inc
Contract Manufacturer	Changzhou Kangdi Medical Stapler Co., Ltd	Ethicon Endo-Surgery, Inc
510(k) Clearance Numbers	Subject of this Notification	K920752
Intended use	Applications throughout the alimentary Tract for end-to-end, end-to-side and Side-to-side anastomoses.	Applications throughout the alimentary Tract for end-to-end, end-to-side and Side-to-side anastomoses.
Contraindications	Same , refer to labeling	Same , refer to labeling
FDA Class(System)	Class II	Class II
Sizes	25.5mm, 28.5mm Circular Staplers	25mm, 29mm Circular Staplers
Staple Shape	B-Shaped	B-Shaped

K100723 Page 3/6

Features &Description	Changzhou Kangdi Medical Stapler Co.,Ltd Disposable Circular Stapler 25.5mm, 28.5mm	Predicate Ethicon Endo-Surgery,Inc. Endopath ILS Endoscopic Circular Stapler 25mm, 29mm
Closed Staple Height	1.5mm-2.0mm	1.0mm-2.5mm
Staple Material	ISO 5832-2: Implants for surgery - Metallic materials - Part 2: Unalloyed Titanium	ISO 5832-2: Implants for surgery - Metallic materials - Part 2: Unalloyed Titanium
Knife Material	Stainless steel	Stainless steel
Stapler Material	Polymeric materials, surgical grade stainless steels and lubricants	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants
Cutting Mechanism	Circular Knife	Circular Knife
DCS Internal Power	None	None
Power	Manually powered	Manually powered
Energy to bend Staple	17.5 N	Similar
Software containing	No	No
Digital Information	None	None
How Supplied	Sterile-Single Patient Use	Sterile-Single Patient Use

K100723 Page 4/6

Features &Description	Changzhou Kangdi Medical Stapler Co.,Ltd Disposable Circular Stapler 25.5mm, 28.5mm	Predicate Ethicon Endo-Surgery,Inc. Endopath ILS Endoscopic Circular Stapler 25mm, 29mm
Safety Mechanism	Contains indicators for appropriate Range for desired closed staple height , but can be deployed out of range	Contains indicators for appropriate Range for desired closed staple height , but can be deployed out of range
Staples per Clip	20 for 25.5; 24 for 28.5	20 for 25mm; 24 for 29mm
Energy to Remove	2.8-4.3 N	Same
Accuracy of B bend per clip	100%	100%
Insertion Mechanism	Rigid	Rigid
Method of Sterilization	Irradiation	Irradiation
Packaging	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid

K100723 Page 5/6

7. Performance Testing Section:

In order to establish substantial equivalence to the identified predicate device's) we performed the following tests: for biocompatibility we performed cytotoxicity, sensitization, irritation and acute systemic toxicity testing and the results of the testing provided evidence that the device was biocompatible. For assessment of device performance characteristics we assured that the device met all performance standards for implanted titanium and for package integrity and shelf life assessments following sterilization we assessed the results of the Tensile Seal Strength Test, Package Verification Test, Vacuum Leak Test, Impermeability Fusion Test, Agar Contact-Attack Test and Accelerated Aging Testing. The results of all of these tests provided evidence that the subject device was substantially equivalent to the predicate device.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Changzhou Kangdi Medical Stapler Co., Ltd. concludes that , models KYGW-25.5 and KYGW-28.5 is substantially equivalent to predicate devices as described herein.

9. Changzhou Kangdi Medical Stapler Co., Ltd. will update and include in a summary any other information deemed seasonably necessary by the FDA.

END

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

Changzhou Kangdi Medical Stapler Co., Ltd.
% International Regulatory Consultants, LLC
Mr. Charlie Mack
77325 Joyce Way
Echo, Oregon, 97826

APR 30 2010

Re: K100723
Trade/Device Name: Disposable Circular Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 7, 2010
Received: March 15, 2010

Dear Mr. Mack:

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

Indications for Use

510(k) Number (if known):

Device Name: Disposable Circular Stapler, Models KYGW-25..5 and KYGW-28.5

Indications for Use:

The Disposable Circular Stapler has application throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.

Prescription Use ___√___ 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

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

510(k) Number K100773