

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: April 22, 2012

JUL 16 2012

Company making the submission:

Name – Changzhou Kangdi Medical Stapler Co., Ltd
Address – No. 167-5, East Road, Changzhou, Jiangsu, China 213022
Telephone – 86-519-85162780
Fax – 86-519-85139853
Contact – Mr. Fleming Jiang
Email – jiangmingfang@kanghui-china.com

Correspondent:

Name: Charles Mack
Address: 77325 Joyce Way, Echo, Oregon 97826
Telephone: 931-625-4938
Email: charliemack@irc-us.com

Device:

Trade/proprietary names:

Disposable Linear Stapler, Model KYFB
Disposable Linear Cutter, Model KYQII

Common Name: Implantable Staple

Classification Name: Staple, implantable

Predicate Devices:

Linear Stapler:

Ethicon Endo-Surgery, Inc.
K020779

The PROXIMATE Reloadable Linear Stapler, Model TL30, TL60, TL90,
TLH30, TLH60, TLH90

Linear Cutter:

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

K111825

DST Series™ GIA™, Auto Suture™ GIA™ Reloadable Stapler, GIA60, GIA80,
GIA100

Classifications Names & Citations:

21CFR 878.4520, GDW, Polymer, ENT synthetic-polyamide (mesh or foil material), Class II

Description:

General

Disposable Linear Stapler

The Disposable Linear Stapler delivers two staggered rows of titanium staples to approximate internal tissues. The instrument is available in three sizes to accommodate different tissues. Staple height is adjustable to compensate for various tissue thickness. The 30 mm instruments create a 30 mm staple line, the 60 mm instruments create a 60 mm staple line, the 90 mm instruments create a 90 mm staple line.

Disposable Linear Cutter

The disposable linear cutter and the cartridge for disposable linear cutter have applications in abdominal gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

Indications For Use

Disposable Linear Stapler, Model KYFB-30 / 60 / 90

The Disposable Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues.

Disposable Linear Cutter, Model KYQII-60 / 80 / 100

The Disposable Linear Cutter has applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

Technical Characteristics:

The Disposable Linear cutter and Disposable Linear cutter have not changed in basic design. The only difference in the current submitted device is the size of the staples. The staples in the submitted device The staple differences are not significant and testing of the staples during insertion and extraction showed that there are no appreciable differences in the energy needed to insert or extract the staples.

Performance data:

In order to establish substantial equivalence to the identified predicate device's, we performed the following tests:

Bench testing was performed to demonstrate the energy to deliver staples and also to remove staples was consistent with the predicate device. ISO 5832-2:1999 Implants for surgery - Metallic materials - Part 2: Unalloyed Titanium and ASTM F67-06 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).

Biocompatibility testing was performed to ensure the stapler and cutters were constructed of material which passes the ISO 10993 benchmarks. The devices successfully passed tests for ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10 and ISO 10993-11.

As these products are delivered sterile, sterility testing was performed to ensure the sterilization methodology was sufficient and that the packaging kept the products sterile for the stated 3 year shelf

life. Testing was performed to ISO 11137-1:2006, ISO 11137-2:2006, ISO 11737-1:2006 and ISO 11737-2:2009, ISO 11607-1:2006, ASTM F1929-98 (2004), ASTM F1980-01 and ASTM D3078-02 (2008) with the products successfully passing all tests.

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 Disposable Linear Stapler, Model KYFB and Disposable Linear Cutter, Model KYQII are substantially equivalent to predicate devices as described herein.

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 Company, LTD
% International Regulatory Consultants, LLC
Mr. Charles Mack
77325 Joyce Way
Echo, Oregon 97826

JUL 16 2012

Re: K121474

Trade/Device Name: Disposable Linear Stapler, Model KYFB-30/60/90, Disposable Linear Cutter, Model KYQII-60/80/100

Regulation Number: 21 CFR 878.4750

Regulation Name: Implantable staple

Regulatory Class: II

Product Code: GDW

Dated: May 13, 2012

Received: May 18, 2012

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

Page 2 - Mr. Charles Mack

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): K121474

510(k) Number (if known):

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kruse for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of _____

510(k) Number K121474