JUN 1 1 2013

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, 2013

Company making the submission:
Name – Changzhou City Zhiye Medical Devices Institute Co., Ltd.
Address – No. 127 Xiacheng Road, Changzhou City, Jiangsu Province, China, 518054
Tel: +86-519-86707185
Fax: +86-519-86707186
Contact – Mrs. Huang Xinying
Email –charliemack@irc-us.com

Correspondent:
Name: Charles Mack
Address: 12226 Washington Lane, Parker, Arizona, 85344
Telephone: 931-625-4938
Email: charliemack@irc-us.com

Device:
Trade/proprietary names: Disposable Circular Stapler, YH-26
Common Name: Implantable Staple
Classification Name: Staple, implantable

Predicate Device:

Circular Stapler:

Endopath ILs Endoscopic Circular Stapler
Ethicon, Inc.
4545 Creek Rd.
Cincinnati, OH 45242 283
K920752

Classifications Names & Citations:
21CFR 878.4750, GDW, Implantable staple, Class II

Description:

General

Disposable Circular Stapler

The disposable circular stapler is preloaded with two staggered rows of 26mm 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.

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.

Technical Characteristics:

The disposable circular stapler is similar in construction and operation to the submitted predicate device. The only difference in the submitted device is the size of the staples. The staples in the submitted device is 26 mm height and is 1.5-2.0 mm compressed, where the predicate staples are offered in 25 and 29 mm heights and when compressed they are 1.5-2.5 mm. 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.

Test Summary:

In order to establish substantial equivalence to the identified predicate device, 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 F1980-07, ASTM F88/F88M-09 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 City Zhiye Medical Devices Institute Co., Ltd. concludes that Disposable Circular Stapler, Model YH-26 is substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 11, 2013

Changzhou City Zhiye Medical Devices Institute Co., Ltd.
% IRC
Mr. Charlie Mack
12226 Washington Lane
Parker, Arizona 85344

Re: K131303
Trade/Device Name: Disposable Circular Stapler, YH-26
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: May 07, 2013
Received: May 07, 2013

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,

For Peter D. Rumm -S

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

Enclosure

Indications for Use

510(k) Number (if known): K131303

Device Name: Disposable Circular Stapler, YH-26

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 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131303