November 30, 2017

Changzhou Kangdi Medical Stapler Co. Ltd.
% Mr. Charlie Mack
Principal Engineer
IRC
2091 Oak Drive
Lake Havasu City, Arizona 86406

Re: K172538
Trade/Device Name: Disposable Linear Stapler, Disposable Linear Cutter
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: August 12, 2017
Received: August 22, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K172538

Device Name
Disposable Linear Stapler
Disposable Linear Cutter

Indications for Use (Describe)
Disposable Linear Stapler:
The Disposable Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transaction and resection of internal tissues.

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

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)
- Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
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: August 13, 2017

Company making the submission:
Name - Changzhou Kangdi Medical Stapler Co., Ltd
Address - No.16 Kunlun Road, XinBei Zone, Changzhou City, Jiangsu Province, China 213022
Telephone - 86-519-85162780
Fax - 86-519-85139853
Contact - Ms. Eve Zhou
Email - charliemack@irc-us.com

Correspondent:
Name: Charles Mack
Address: 2091 Oak Drive, Lake Havasu City, Arizona 86406
Telephone: 931-625-4938
Email: charliemack@irc-us.com

Device:
Trade/proprietary names:

<table>
<thead>
<tr>
<th>Disposable Linear Stapler</th>
<th>KFD-30L, KFD-30H, KFD-45L, KFD-45H, KFD-60L, KFD-60H, KFD-90L, KFD-90H</th>
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</table>

<table>
<thead>
<tr>
<th>Disposable Linear Cutter</th>
<th>KYQ-60L, KYQ-60H, KYQ-80L, KYQ-80H, KYQ-100L, KYQ-100H</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>KYQB-60L, KYQB-60H, KYQB-80L, KYQB-80H, KYQB-100L, KYQB-100H</td>
</tr>
</tbody>
</table>

Common Name: Implantable Staple
Classification Name: Staple, implantable
Predicate Device:
This submission is a modification to the previously cleared Changzhou Kangdi Medical Stapler Co., Ltd Disposable Linear Cutter and Disposable Linear Stapler under 510(k) number K121474 with a decision date on 07/16/2012.

Classification
21 CFR 878.4750, Implantable staple, Class II, GDW

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 a variety of sizes to accommodate different tissues. Staple height is adjustable to compensate for various tissue thickness. The model number defines the staple line. For example, the 30 mm instruments create a 30-mm staple line, the 45 mm instruments create a 45-mm staple line, the 60 mm instruments create a 60-mm staple line and 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:
The Disposable Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transaction and resection of internal tissues.

Disposable Linear Cutter:
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. There is no change to the staples in material or structure. The only difference in the current submitted device is the firing knob and the handles. 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, the following tests were performed:
Bench testing was performed to demonstrate the energy to deliver staples and also to remove staples was consistent with the predicate device.

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.

The modifications to the devices have not affected the sterility process, materials or packaging. For verifications, packaging and sterility verifications were completed.

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