December 5, 2017

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

Re: K172561
Trade/Device Name: Disposable Circular Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: October 29, 2017
Received: November 7, 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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172561

Device Name
Disposable Circular Stapler

Indications for Use *(Describe)*
The Disposable Circular Stapler has application throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.

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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"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: November 2, 2017

Company making the submission:
Name – Changzhou Kangdi Medical Stapler Co., Ltd
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Jiangsu Province,
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Contact – Ms. Eve Zhou
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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:

Disposable Circular Stapler	Model KYGWA- 23.5 / 25.5 / 28.5 / 31.5 / 33.5; Model KYGWB- 23.5 / 25.5 / 28.5 / 31.5 / 33.5; Model KYWC- 17.5 / 21.5 / 23.5 / 25.5 / 28.5 / 31.5 / 33.5

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 Circular Stapler under 510(k) number K100723 with a decision date on

04/30/2010.

Classifications Names & Citations:
Classification of the device: Class II
Panel: General and Plastic Surgery
Product code: GDW, 21CFR878.4750

Description:
General
The Disposable Circular Staplers, can anastomose organs by firing into the tissues of alimentary canal two staggered (interior and exterior) rings of titanium staples and cutting off inside tissue with the circular blades simultaneously.
The disposable circular stapler is preloaded with two staggered rows of titanium staples in both inner and outer circles. The instrument is activated by squeezing the handles firmly as far as they will go. Immediately after staple formation, the knife blade resects the excess tissue, creating a circular anastomosis.

Indications For Use
Disposable Circular Stapler:
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 has not changed in basic design. The only difference in the current submitted device is there are new models, using different staple sizes. The KYGWG stapler has a new adjusting nut shape, which does not affect performance. 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 Test Summary:
The implanted staple is the same material as the predicate device and meets the Standard for Unalloyed Titanium for Surgical Implant Applications.
There is no FDA recognized performance standard for implanted staple and stapler. Therefore, the same testing submitted for the predicate was repeated. The testing was as follows:

1. Visual appearance
2. Dimensions
3. Sharpness
4. Operational Performance
5. Cutting Performance
6. Staple formation and closed staple height
7. Pressure resistance
8. Corrosion resistance
9. Packaging performance
10. Hardness
11. Firing Force
12. Energy Testing
13. Sterility

Biocompatibility testing was performed to ensure the stapler was constructed of material which passes the Biological Evaluation of Medical Devices, parts 1,3,5,6, 10 and 11.
The modifications to the devices have not affected the sterility process, materials or packaging. For verifications, packaging and sterility verfication was completed per USP standards.

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 Circular Stapler, Models KYGWA/KYGWB/KYGWC are substantially equivalent to predicate devices as described herein.

END