DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 12, 2015

B. J. Zh. F. Panther Medical Equipment Company, Ltd
% Ms. Diana Hong
Mid-link Consulting Company, Ltd
P.O. Box 120-119
Shanghai, 200120 China

Re: K152618
Trade/Device Name: PANTHER Cutter Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: September 1, 2015
Received: September 14, 2015

Dear Ms. Hong:

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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152618

Device Name
PANTHER Cutter Stapler

Indications for Use *(Describe)*
The PANTHER Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

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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510(k) Summary

510(k) Submitter

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Date Prepared: 10/08/2015

Device Names/Classification

Trade Name: PANTHER Cutter Stapler
Common Name: Cutter stapler and reloads

Classification Name: Staple, Implantable;
Classification: II;
Product Code: GDW;
Regulation Number: 21CFR 878.4750
Review Panel: General & Plastic Surgery;

Classification Name: Stapler, Surgical;
Classification: II;
Subsequent Product Code: GAG;
Regulation Number: 21CFR 878.4880
Review Panel: General & Plastic Surgery

Predicate Devices

510(k) Number: K091322
Product Name: CONTOUR™ Curved Cutter Stapler and Reloads

Device Description

The proposed device, PANTHER Cutter Stapler, is sterilized and disposable surgical instruments, which is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedure.

It delivers four staggered rows of titanium staples with a knife that divides the tissue simultaneously

between the second and third row of staples. The PANTHER Cutter Stapler may be reloaded and fire no more than 6 times in a single procedure.

Indications for Use

The PANTHER Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

Differences in Technological Characteristic

The PANTHER Cutter Stapler is identical to the CONTOUR™ Curved Cutter Stapler and Reloads marketed device with respect to technological characteristics. The PANTHER Cutter Stapler has the same intended use, configuration, operation principle, staple height, patient-contact material, sterilization as the predicate device.

Summary of Performance Testing

Pre-Clinical
No study is included in this submission.
Bench
Bench tests including Physical Specification, Closed Staple Height Dimensions, Pressure Resistance, Maximum Tensile Strength and Force Required to Fire Stapler were conducted to confirm that the proposed devices perform as intended and are substantially equivalent to the predicate devices.
Animal
No animal study is included in this submission.
Clinical
No clinical study is included in this submission.

Conclusion

Based on performance data, the proposed devices is substantially equivalent to the predicate devices CONTOUR™ Curved Cutter Stapler and Reloads cleared in K091322.