

**Section 5 - 510(k) Summary**

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JAN 24 2014

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**3. Date Prepared**

November 12, 2013

**4. Device Identification**

Trade/Proprietary Name: Suzhou Beinuo family of Surgical Staplers  
Common/Usual Name: Staple, Implantable  
Classification Name: Implantable staple  
Classification Regulation: 21CFR 878.4750  
Product Code: GDW  
Device Class: Class II  
Classification Panel: General and Plastic Surgery

**5. Predicate Devices**

The Suzhou Frankenman Surgical Staplers (K101378) which includes:

- Disposable Alimentary Canal Staplers;
- Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids;
- Disposable Reloadable Linear Stapler and Reloads; and
- Disposable Reloadable Linear Cutter Stapler and Reloads;

The Frankenman Surgical Staplers are substantially to the Suzhou Beinuo family of surgical staplers. The Suzhou Beinuo surgical staplers are virtually identical to the predicate device(s) described above.

## 6. Device Description

The Suzhou Beinuo Staplers were designed in reference to the general principles of surgical staplers. Each stapler/ instrument is activated by squeezing the handle firmly as far as it will go or by pushing the firing knob as far as it will go. Specifics for each stapler include:

- The Suzhou Beinuo Circular Stapler for Single Use places a circular, double staggered row of titanium staples. Immediately after staple formation, the instrument's central knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. Note that there are two product codes for this stapler (SBW and SBCS L). The total length of SBW stapler is 420mm and the total length of SBCS L version is 520mm. The staplers are identical except for the length.
- The Suzhou Beinuo Hemorrhoidal Circular Staplers for Single Use places two circular peripheral lines of alternating and overlapping staples, thereby sealing off the rectal tissue above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal tissue. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.
- The Suzhou Beinuo Linear Staplers and Reloads for Single Use places a double(or triple in the case of the SBF 30B) staggered row of titanium staples used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.
- The Suzhou Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.

## 7. Intended Use

Suzhou Beinuo surgical staplers are indicated for use as follows:

- **Circular Stapler for Single Use**  
 The Suzhou Beinuo Circle Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.

- Hemorrhoidal Circular Stapler for Single Use**  
 The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.
- Linear Stapler and Reloads for Single Use**  
 The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, and thoracic surgical procedures.
- Linear Cutter Stapler and Reloads for Single Use**  
 The Suzhou Beinuo Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, and thoracic surgical procedures.

**8. Comparison of Technological Characteristics**

The following table compares the Suzhou Beinuo family of surgical staplers to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

**Table 5A – Comparison of Characteristics**

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
510(k) Number	TBD	K101378	n/a
Product Code	GDW	GDW	Identical
Regulation Number	21CFR 878.4750	21CFR 878.4750	Identical
Regulation Name	Implantable staple	Implantable staple	Identical
Indications for Use	<p><b>Circular Stapler for Single Use</b>            The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.</p> <p><b>Hemorrhoidal Circular Stapler for Single Use</b>            The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment</p>	<p><b>Disposable Alimentary Canal Stapler</b>            The Frankenman Disposable Alimentary Canal Stapler is used throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic techniques.</p> <p><b>Single Use Circular Stapler for Rectal Prolapse and Hemorrhoid</b>            The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids is a Circular Stapler product, with accessories, that has</p>	<p>Virtually Identical</p> <p>Essentially identical. Suzhou Beinuo indication and the Frankenman indications discuss the same procedures. No safety or efficacy impact to the difference in wording</p>

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>of hemorrhoids and anorectal wall defects.</p> <p><b>Linear Stapler and Reloads for Single Use</b>            The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, and thoracic surgical procedures.</p> <p><b>Linear Cutter Stapler and Reloads for Single Use</b>            The Suzhou Beinuo Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, and thoracic surgical procedures</p>	<p>application for general surgical treatment of haemorrhoids and anorectal wall defects by means of transanal stapling and resection of mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position.</p> <p><b>Disposable Reloadable Linear Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Stapler (and Reloads) is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.</p> <p><b>Disposable Reloadable Linear Cutter Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Cutter Stapler (and Reloads) has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.</p>	<p>Essentially identical. Suzhou Beinuo Indication and the Frankenman indication discuss the same procedures. No safety or efficacy impact to the difference in wording</p> <p>Essentially identical. Suzhou Beinuo Indication and the Frankenman indication discuss the same procedures. No safety or efficacy impact to the difference in wording</p>
<p><b>Product Descriptions</b></p>	<p><b>Circular Staplers for Single Use</b>            The Circular Stapler for Single Use is a surgical device for the reconstruction of alimentary tract with mechanical method to replace traditional hand operation.            This device is designed on the principal of staplers. It creates side to end, end to end anastomosis in alimentary canal with peripheral double</p>	<p><b>The Frankenman Disposable Alimentary Canal Stapler (i.e., CS Stapler, is primarily composed of plastic, titanium, and stainless steel and is used for the reconstruction and anastomosis in the alimentary canal. These disposable staplers place a circular, double staggered row of titanium (ISO 5832-2) staples and then resect the excess tissue, creating a circular</b></p>	<p>The products are virtually identical.</p>

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>staggered rows of staples, and cut off the residue tissue with the circular cutting blade in the center to ensure a big enough canal for the reconstructed alimentary tract. By squeezing the firing handle, the staples form and the circular knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler.</p> <p>The Circular Stapler for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The Circular Stapler for Single Use is used for reconstruction and anastomosis in the alimentary canal. The device has a shelf-life of 3 years.</p> <p><b><u>Hemorrhoidal Circular Stapler for Single Use</u></b></p> <p><b>Product description</b></p> <p>Hemorrhoidal Circular Staplers for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The product's shelf life is 3 years.</p>	<p>anastomosis. The CS Stapler is activated by squeezing the handle firmly.</p> <p>The outer diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. The stapler is available in one staple diameter, 0.28mm and two shaft lengths, 420mm and 520mm.</p> <p><b>The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids</b> (i.e., stapled Haemorrhoidopexy (CPH), is primarily manufactured from plastic, titanium, aluminum alloy and stainless steel and is used in the treatment of rectal haemorrhoids and anorectal defects of transanal stapling (otherwise known as <u>staples transanal rectal resection</u> or STARR procedure) and</p>	

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>Hemorrhoidal Circular Staplers for Single Use is used in the treatment of rectal wall defects and internal hemorrhoids during anorectal surgery. The Beinuo Hemorrhoidal Circular Staplers for Single Use places a circular, double staggered rows of titanium staples, thereby sealing off the rectal mucosa or rectum above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa or rectum. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.</p> <p><b><u>Linear Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Stapler and Reloads for Single Use are made of plastic particles, titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Staplers and Reloads for Single Use is used in the closure of incision and stump of inner organs in general surgery. The shelf life is 3 years.</p> <p>The Beinuo Linear Staplers and Reloads for Single Use places a double staggered row of titanium staples (3 rows for white cartridge only) used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm,</p>	<p>resection of rectal mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position. Specifically, the rectal mucosa above the anal canal is sealed by the placement of two circular peripheral lines of alternating and overlapping of titanium (ISO 5832-2) staples. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.</p> <p><b>The Frankenman Disposable Reloadable Linear Stapler</b> is manufactured primarily from plastic, titanium, and stainless steel. Single Use, reloadable linear staplers are used in the process of mechanical suturing and closure of tissue, prior to the removal of excess tissue. Specific surgical procedures where the LS would be used include general, thoracic, gynecological and colorectal surgeries.</p> <p>The LS places a double staggered row of titanium (ISO 5832-2) staples, with the exception of model number LS30W which places three staggered rows of staples. This third row provides additional security for closing vessels where bleeding is a significant risk.</p>	

Manufacturer	Suzhou Beينو	Suzhou Frankenman	Significant Differences
	<p>46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.</p> <p><b><u>Linear Cutter Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Cutter Staplers and Reloads for Single Use are made of plastic particles, pure titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Cutter Staplers and Reloads for Single Use is used in transection, resection and suture in GI, gynecological, thoracic surgeries. The shelf is three years.</p> <p>The Beينو Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.</p>	<p>The LS is available in 30mm, 45mm, 60mm, and 90mm staple line lengths for use in various applications and three stapler sizes (2.5, 3.8mm and 4.5mm) to accommodate various tissue thicknesses.</p> <p><b>The Frankenman Disposable Reloadable Linear Cutter Stapler (i.e. LC Stapler)</b></p> <p>The Frankenman LC Disposable Reloadable Stapler delivers two doubled staggered rows of titanium staples and is used to resect and/or anastomose the internal tissues during surgical procedures and reloads are manufactured primarily from plastic, titanium, and stainless steel. The Frankenman Disposable Reloadable Linear Cutter stapler is used for abdominal, gynecological, thoracic, and pediatric surgery for transaction, resection, and the creation of anastomoses</p>	
<b>Basic Principle of Operation</b>	The stapler places a circular, double-staggered row of staples and then resects any excess tissue, creating a circular anastomosis.	Stapler places a circular, double staggered row of staples and then resects the excess tissue, creating a circular anastomosis.	Identical

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
<b>Material</b>	Stainless steel (staplers) & titanium (staples)	Stainless steel (staplers) & titanium (staples)	Identical
<b>Sterile</b>	Yes, radiation sterilized	Yes, radiation sterilized	Identical
<b>Single-Use</b>	Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization).	Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization).	Identical
<b>Shelf Life</b>	36 months based on the sterilization validation of the packaging.	24 months based on sterilization validation of the packaging	The Suzhou Beinuo device has 12 months additional shelf life based on sterilization validation data.
<b>Biocompatibility</b>	Complies with ISO 10993-1 and other pertinent standards	Complies with ISO 10993-1 and other pertinent standards	Identical
<b>Conclusion:</b> The Suzhou Beinuo surgical staple device shares the same indications for use, device operation, overall technical and functional capabilities, meets the same standards and requirements and therefore are substantially equivalent to the predicate device(s). The Suzhou Beinuo device is similar in design and function to the predicate devices for the modes of operation and use.			

## 9. Non-Clinical Performance Data

The Suzhou Beinuo surgical stapler complies with the applicable voluntary standards as shown below:

- Materials of Construction – ISO 5382-2-1999 – Surgical Instruments – Metallic Materials – Part 2 – Unalloyed titanium
- Sterilization –
  - ISO 11737-1: 2006, Sterilization of medical devices -- Microbiological methods – Part 1, Determination of a population of microorganisms on products
  - ISO 11137-1:2006, Sterilization of healthcare products – Radiation – Part 1, Requirements for the development, validation and routine control of a sterilization process for medical devices.
- Biocompatibility – contact materials were tested per the schema in ISO 10993-1. Specifically:
  - AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
  - ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)
- Risk Management activities were carried out as described in ISO 14971: 2007, Medical devices -- Application of risk management to medical devices
- Packaging for Terminally Sterilized Devices – ISO 11607:2003, Packaging for Terminally Sterilized Medical Products.

Additionally, the surgical staplers were evaluated to validate physical characteristics (appearance, dimensions, stapler compatibility with the cartridge) and performance characteristics (strength, closure performance). The Suzhou Beinuo staplers were also evaluated for performance testing compared to the analogous Suzhou Frankenman staplers. Evaluation of the two stapler products similar results (in terms of post-operative healing, pain management, anastomotic leakage, and bleeding) as compared to manual suturing and competitors' devices.

Based on this testing, the design and construction of the Suzhou Beinuo and Suzhou Frankenman staplers were determined to be substantially equivalent. The Suzhou Beinuo family of surgical staplers meets all the requirements for overall design, sterilization, biocompatibility, and clinical utility confirming that the output meets the design inputs and specifications. The Suzhou Beinuo surgical staplers passed all testing and supports the claims of substantial equivalence and safe operation.

The Suzhou Beinuo surgical staplers comply with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

#### **10. Clinical Testing**

There was no prospective clinical studies required to support the medical device as the indications for use, technology, materials of construction are virtually identical to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

#### **11. Statement of Substantial Equivalence**

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

It has been shown in this 510(k) submission that the difference between the Suzhou Beinuo surgical staplers and the Suzhou Frankenmann surgical staplers do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the Suzhou Beinuo surgical staplers are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. The Suzhou Beinuo surgical staplers, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.



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

January 14, 2014

Suzhou Beinuo Medical Equipment Co., Ltd.  
C/O Emergo Group  
Robert Seiple, RAC, Senior Consultant, QA/RA  
816 Congress Avenue, Suite 1400  
Austin, Texas 78701

Re: K133499

Trade/Device Name: Suzhou Beinuo Family of Surgical Staplers  
Regulation Number: 21 CFR 878.4750  
Regulation Name: Implantable staple  
Regulatory Class: Class II  
Product Code: GDW  
Dated: November 13, 2013  
Received: November 14, 2013

Dear Mr. Seiple:

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/ucml15809.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,

Binita S. Ashar, MD, MBA, FACS  
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Binita Ashar, MD, MBA, FACS  
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)  
K133499

Device Name  
Suzhou Beinuo Surgical Staplers

Indications for Use (Describe)

Suzhou Beinuo surgical staplers are indicated for use as follows:

• Circular Stapler for Single Use

The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.

• Hemorrhoidal Circular Stapler for Single Use

The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.

• Linear Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Stapler and Reloads for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, and thoracic surgical procedures.

• Linear Cutter Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Cutter Stapler and Reloads for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**David Krause -S**