K101378

510(k) Summary

(per 21 CFR 807.92(c))

JUN 2 9 2010

1. Applicant

Suzhou Frankenman Medical Equipment Co., Ltd.
88 Jinfeng Road
High-new District
Suzhou 215011
China

Contact Person: Zhou Tiejun, Office Manager
Tel: 86 512 6878 6125
Fax: 86 512 6808 0025
E-mail: manager@frankenman.com

Date Prepared: April 12, 2010

2. Device Name

Trade Name:	Frankenman Family of Surgical Staplers
Common/ Usual Name:	Staple, Implantable
Classification Name:	Implantable Staple
Regulation Number:	878.4750
Product Code:	GDW
Classification:	II
Panel:	General & Plastic Surgery

3. Predicate Devices

The Frankenman Surgical Staplers which include:

- 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;

are substantially equivalent to the devices listed in Table 1. In fact, the Frankenman Staplers are identical to the Chex Staplers with the exception of the manufacturer and product names as listed on the labeling.

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Subject Device	Predicate Device		
	Name	Company	510(k) Number
Disposable Alimentary Canal Staplers	Chex™ Single Use Curved Intraluminal Circular Stapler	Frankenman™ International Limited	K090821
	Endopath ILS Endoscopic Circular Stapler	Ethicon	K920752
Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids	Chex™ Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids	Frankenman™ International Limited	K090821
Disposable Reloadable Linear Stapler and Reloads	Chex™ Single Use Reloadable Linear Stapler and Reloads	Frankenman™ International Limited	K090821
	Disposable Linear Stapler (LSF)	Ethicon	K822345
Disposable Reloadable Linear Cutter Stapler and Reloads	Chex™ Linear Cutter Disposable Reloadable Stapler	Frankenman™ International Limited	K090821

4. Indications for Use

The indications for use for the Frankenman Family of Staplers include:

- **Disposable Alimentary Canal Stapler**
  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.
- **Single Use Circular Stapler for Rectal Prolapse and Hemorrhoid**
  The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids is a Circular Stapler product, with accessories, that has 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.
- **Disposable Reloadable Linear Stapler and Reloads**
  The Frankenman Disposable Reloadable Linear Stapler is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.
- **Disposable Reloadable Linear Cutter Stapler and Reloads**
  The Frankenman Disposable Reloadable Linear Cutter Stapler has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.

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- **Disposable Reloadable Linear Stapler and Reloads**
  The Frankenman Disposable Reloadable Linear Stapler is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.
- **Disposable Reloadable Linear Cutter Stapler and Reloads**
  The Frankenman Disposable Reloadable Linear Cutter Stapler has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.

5. Description of the Devices

The Frankenman 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. Specifics for each stapler include:

- The Frankenman Disposable Alimentary Canal Stapler places a circular, double staggered row of titanium staples. Immediately after staple formation, the instrument's 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.
- The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids places two circular peripheral lines of alternating and overlapping staples, thereby sealing off the rectal mucosa above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.
- The Frankenman Disposable Reloadable Linear Stapler places a double(or triple in the case of the LS30-W) staggered row of titanium staples used for mechanical suturing and closure of tissue, prior to the removal of excess tissue. The Linear Stapler is available in 30mm, 45mm, 60mm, and 90mm line lengths for use in various applications. The instrument may be reloaded during a single procedure but cannot be reloaded more than seven times for a maximum of eight firings per instrument.
- The Frankenman Disposable Reloadable Linear Cutter Stapler 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 but cannot be reloaded more than seven times for a maximum of eight firings per instrument. The use of the instrument with staple buttressing materials, or across a previous staple line, may reduce the number of firings.

6. Summary of Performance Data

Suzhou Frankenman tested each stapler to validate both physical (i.e., appearance, dimensions, stapler compatibility with cartridge, sterility per ISO 11737 and EN 552) and performance characteristics (strength, closure performance). In addition, a performance test was conducted comparing the Frankenman Disposable Alimentary Canal Stapler and the Frankenman Disposable Reloadable Linear Stapler to analogous Ethicon staplers. Based on this test, the design and construction of the Frankenman and Ethicon staplers were determined to be substantially equivalent. Finally, clinical testing of each stapler line produced superior results (in terms of post-operative healing, pain management, anastomotic leakage, and bleeding) as compared to manual suturing and competitors' devices.

7. Safety & Effectiveness

There are no substantial differences between the Frankenman Family of Staplers defined in this 510(k) submission and the predicate devices. They have the same or similar Indications for Use. In addition, the minor differences in technological characteristics do not raise issues of safety and effectiveness.

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The Frankenman 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. Specifics for each stapler include:

- The Frankenman Disposable Alimentary Canal Stapler places a circular, double staggered row of titanium staples. Immediately after staple formation, the instrument's 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.
- The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids places two circular peripheral lines of alternating and overlapping staples, thereby sealing off the rectal mucosa above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.
- The Frankenman Disposable Reloadable Linear Stapler places a double(or triple in the case of the LS30-W) staggered row of titanium staples used for mechanical suturing and closure of tissue, prior to the removal of excess tissue. The Linear Stapler is available in 30mm, 45mm, 60mm, and 90mm line lengths for use in various applications. The instrument may be reloaded during a single procedure but cannot be reloaded more than seven times for a maximum of eight firings per instrument.
- The Frankenman Disposable Reloadable Linear Cutter Stapler 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 but cannot be reloaded more than seven times for a maximum of eight firings per instrument. The use of the instrument with staple buttressing materials, or across a previous staple line, may reduce the number of firings.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Suzhou Frankenman Medical Equipment Co., Ltd
% Emergo Group, Inc.
Jean Asquith
1705 S. Capital of Texas Highway, Suite 500
Austin, Texas 78746

JUN 2 9 2010

Re: K101378
Trade/Device Name: Frankenman Surgical Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: April 12, 2010
Received: May 21, 2010

Dear Jean Asquith:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K101378

Device Name: Frankenman Surgical Staplers

Indications for Use:

Frankenman Staplers are indicated as follows:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	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)

Daniel Kraus for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101378