K090821
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510(k) Summary
(per 21 CFR 807.92(c))

JUN 10 2009

1. Applicant

Frankenman International Limited
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Sheung Wan, Hong Kong
China

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Date Prepared: March 1, 2009

2. Device Name

Trade Name: Chex™ 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 Chex™ Family of Surgical Staplers, which include:
- Single Use Curved Intraluminal Circular Stapler,
- Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids,
- Single Use Reloadable Linear Stapler and Reloads, and
- Single Use Reloadable Linear Cutter Stapler and Reloads

are substantially equivalent to:

Subject Device	Predicate Device		
	Name	Company	510(k) Number
Chex™ Single Use Curved Intraluminal Circular Stapler	Endopath ILS Endoscopic Circular Stapler	Ethicon	K920752
	Autosuture™ Circular EEA Surgical Staplers	United States Surgical Corp. (USSC)	K062850
	Autosuture™ Premium Plus CEEA Disposable Staplers		K024275
			K020804
			K001895
Chex™ Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids	Proximate PPH Hemorrhoidal Circular Stapler and Accessories	Ethicon Endo-Surgery, Inc.	K051301

Subject Device	Predicate Device		
	Name	Company	510(k) Number
	Hemorrhoidal Circular Stapler and Accessories		K991030
	Hemorrhoidal Circular Stapler and Accessories		K030925
Chex™ Single Use Reloadable Linear Stapler and Reloads	Disposable Linear Stapler (LSF)	Ethicon	K822345
	Auto Suture™ TA premium™	USSC	K905106
Chex™ Linear Cutter Disposable Reloadable Stapler	Auto Suture™ Disposable GIA™ Surgical Stapler	USSC	K801590
	Proximate Linear Cutters and Stapler (not Endopath)	Ethicon Endo-Surgery, Inc.	K951546

4. Intended Use

The Chex Family of Staplers and there intended uses are as follows:

- **Single Use Curved Intraluminal Circular Stapler**

  The CHEX™ Single Use Curved Intraluminal Circular 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.

- **Circular Stapler for Rectal Prolapse and Hemorrhoid**

  The CHEX™ 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.

- **Single Use Reloadable Linear Stapler**

  The CHEX™ Single Use Reloadable Linear Stapler is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.

- **Single Use Reloadable Linear Cutter Stapler**

  The CHEX™ Single Use 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 Chex™ 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 Chex™ Single Use Curved Intraluminal Circular 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 Chex™ 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 Chex™ Disposable Reloadable Linear Stapler places a double 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 Chex™ Linear Cutter Disposable Reloadable 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 100mm). 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

Each of the four Chex™ Staplers were tested and passed all required biocompatibility testing. Specifically, cytotoxcity, skin irritation, and delayed contact sensitization were conducted in accordance with ISO 10993. Secondly, 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). Thirdly, a performance test was conducted comparing the Chex™ Single Use Curved Intraluminal Circular Stapler and the Chex™ 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 Chex™ 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2009

Frankenman International Limited
% Emergo Group, Incorporated
Ms. Jean Asquith
Senior Consultant, Regulatory Affairs
1705 South Capitol of Texas Highway, Suite 500
Austin, Texas 78746

Re: K090821
Trade/Device Name: CHEX™ Surgical Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: March 6, 2009
Received: March 30, 2009

Dear Ms. 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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K090821

Device Name: CHEX™ Surgical Staplers

Indications for Use:

The Chex Family of Staplers and there intended uses are as follows:

1. **Single Use Curved Intraluminal Circular Stapler**
   The CHEX™ Single Use Curved Intraluminal Circular 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.

2. **Circular Stapler for Rectal Prolapse and Hemorrhoid**
   The CHEX™ 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.

3. **Single Use Reloadable Linear Stapler**
   The CHEX™ Single Use Reloadable Linear Stapler is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.

4. **Single Use Reloadable Linear Cutter Stapler**
   The CHEX™ Single Use Reloadable Linear Cutter Stapler has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
X		_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MXM

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

510(k) Number K090821