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 ___X___ (Part 21 CFR 801 Subpart D) 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)

David Krause for MXM

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

510(k) Number K090821