Kapp Surgical Instrument Co, Inc.
4919 Warrensville Center Rd.
Cleveland, OH 44128

Attachment 1A1 – 510(k) Summary

Summary Information:

JAN 13 2006

Applicant: Kapp Surgical Instrument Co., Inc.
4919 Warrensville Center Road
Cleveland, Ohio 44128
Tel: (216) 587-4400
Fax: (216) 587-0411

Contact : Albert Santilli, President

Prepared: October 20, 2005

Device Identification:

Proprietary Name: KAPP Bari-Ring Endoscopic Marker

Common Name: Implantable radiographic marker

Classification Name and Regulation: Implantable clip, product code NEU
21 CFR 878.4300

Predicate Device(s): Med-Edge

Device Description:

The KAPP Bari-Ring Endoscopic Marker consists of a stainless steel ring deployed during surgery supplied non-sterile for single long term use to radiographically (limited to x-ray) mark the site of gastropexy performed during bariatric or other surgical procedures, especially in those procedures where the stomach is not accessible by other diagnostic means (contrast or endoscopy).

Indications for use:

The KAPP Bari-Ring Endoscopic Marker is intended to be used to radiographically (limited to x-ray) mark the site of gastropexy performed during bariatric or other surgical procedures, especially in those procedures where the stomach is not accessible by other diagnostic means (contrast or endoscopy) .

Comparison to the Predicate Devices:

The legally marketed predicate devices to which this device is substantially equivalent are:
K971966, Med-Edge Coronary Vein Graft Tag Marker
K895369, Voss Graft Marker

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Attachment 1A1 – 510(k) Summary (continued)

Attribute	KAPP Bari-Ring Endoscopic Marker	Med-Edge Coronary Vein Graft Tag Marker	Voss Graft Marker
Intended Use			
Intended to be used for radiographically marking the site of surgery during the surgical procedure for future surgical procedures.	YES	YES	YES
Single use device	YES	YES	YES
Design			
Same materials for invasive contact well-known biocompatible industry standard	YES	YES	YES
Performance standards / Specifications			
Biocompatibility testing, and bench testing support fact that no new issues of safety, effectiveness, or performance raised	YES	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Mr. Albert N. Santilli
President
KAPP Surgical Instrument Co., Inc.
4919 Warrensville Center Road
CLEVELAND OH 44128

Re: K050384
Trade/Device Name: KAPP Bari-Ring Endoscopic Marker
Regulation Number: 21 CFR §878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: January 5, 2006
Received: January 6, 2006

Dear Mr. Santilli:

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 (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Kapp Surgical Instrument Co, Inc.
4919 Warrensville Center Rd.
Cleveland, OH 44128

Indications for Use

510(k) Number (if known): K050384

Device Name: KAPP Bari-Ring Endoscopic Marker

Indications for Use:

The KAPP Bari-Ring Endoscopic Marker is intended to be used to radiographically (limited to x-ray) mark the site of gastropexy performed during bariatric or other surgical procedures, especially in those procedures where the stomach is not accessible by other diagnostic means (contrast or endoscopy)

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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050384