Attachment 1 – 510(k) Summary

JUL 28 2004

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, upon which the substantial equivalence determination is based.

Summary Information:

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

Contact : Albert Santilli, President

Prepared: October 31, 2003

Device Identification:

Proprietary Name: Kapp Patient Matched Ulnar Head Wrist Implant

Common Name: Ulnar Head Implant

Classification Name and Regulation: Prosthesis, Wrist joint, Hemi-wrist, 21 CFR 888.3810, 87KXE

Predicate Device(s): Avanta Ulnar Head Implant

Device Description:

The Kapp Patient Matched Ulnar Head Wrist Implant includes various sizes of implants and accessory surgical instruments. The implant allows for replacement of the ulnar head.

Indications for use:

The KAPP Patient Matched Ulnar Head Wrist Implant is intended to be used for:

- Replacement of the distal radioulnar joint following ulnar head resection arthroplasty:
- Replacement of the radial head for degenerative, rheumatoid, or post-traumatic disabilities presenting pain and weakness of the wrist joint and resistance to conservative treatment;
- Instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes, and
- Failed ulnar head resection.

It is intended for patient matched use with bone cement and or press-fit fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2004

Albert N. Santilli, Ph.D.
President
Kapp Surgical Instrument, Inc.
4919 Warrensville Center Road
Warrensville Heights, Ohio 44128

Re: K033930
Trade/Device Name: KAPP Surgical Instrument, Inc. Patient Matched Ulnar Wrist Implant
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: II
Product Code: KXE
Dated: June 18, 2004
Received: June 21, 2004

Dear Dr. 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.

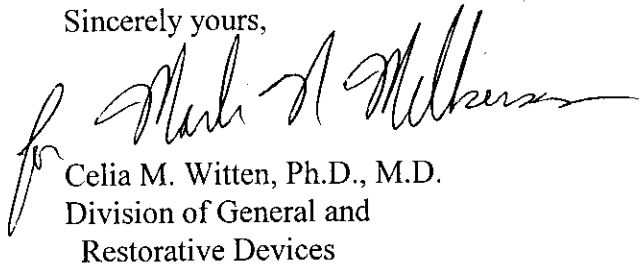
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3 – Statement of Indications for Use

510(k) Number: K03-3930

Device Name: KAPP Surgical Instrument, Inc. Patient Matched Ulnar Wrist Implant

Intended Use / Indications for Use:

The KAPP Patient Matched Ulnar Head Wrist Implant is intended to be used for:

- Replacement of the distal radioulnar joint following ulnar head resection arthroplasty:
- Replacement of the radial head for degenerative, rheumatoid, or post-traumatic disabilities presenting pain and weakness of the wrist joint and resistance to conservative treatment;
- Instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes, and
- Failed ulnar head resection.
- It is intended for patient matched use with bone cement and or press-fit fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE/CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033930

Prescription Use X (per 21 CFR 801.109) OR Over the Counter Use ___ Optional Format 1-2-96