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Attachment 1 – 510(k) Summary

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:	January 22, 2003

Device Identification:

Proprietary Name:	Kapp Custom Radial Head Elbow Implant
Common Name:	Radial Head Implant
Classification Name and Regulation:	Prosthesis, Elbow, Hemi-radial, polymer, 21 CFR 888.3170, 87KWI
Predicate Device(s):	Avanta Radial Head Implant and Wright Medical Metallic Radial Head Implants

Device Description:

The Kapp Custom Radial Head Elbow Implant includes various sizes of implants and accessories including sizers. The implant allows for replacement of the proximal radial head.

Indications for use:

The KAPP Custom Radial Elbow Implant is intended to be used for: replacement of the proximal end of the radius: Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and or proximal radio-ulnar joint with either joint destruction or subluxation visible on x-ray and or resistance to conservative treatment; primary replacement after fracture of the radial head; symptomatic sequelae after radial head resection; revision following failed radial head arthroplasty. It is intended for custom single use with bone cement.

Comparison to the Predicate Devices:

The legally marketed predicate devices to which this device is substantially equivalent is the Avanta Radial Head Implant and Wright Medical Technologies Metallic Radial Head Implants.

Attribute	Candidate Device	Predicate Devices	
Product Name	Kapp Custom Radial Head Elbow Implant	Advanta Radial Head Implant	WMT Metallic Radial Head Implants
Use	Single Use	Single Use	Single Use
Fixation	Intermedulary Canal Stem	Intermedulary Canal Stem	Intermedulary Canal Stem
Contraint	Non-constrained	Non-constrained	Non-constrained
Material	316L Stainless Steel	Co-Cr/CpTi	Ti, Ti6Al4V, Co-Cr
Sizes	6 custom sizes – 2, 2.5, 3, 4, 5, and 6	3 sizes: 1, 2, 3	7 sizes: 0, 1, 1.5, 2, 2.5, 3, 4
Indications for use:	The KAPP Custom Radial Elbow Implant is intended to be used for: replacement of the proximal end of the radius: Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and or proximal radio-ulnar joint with either joint destruction or subluxation visible on x-ray and or resistance to conservative treatment; primary replacement after fracture of the radial head; symptomatic sequelae after radial head resection; revision following failed radial head arthroplasty. It is intended for custom single use with bone cement.	The Advanta Radial Head Implant is intended for: replacement of the proximal end of the radius: Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and or proximal radio-ulnar joint with either joint destruction or subluxation visible on x-ray and or resistance to conservative treatment; primary replacement after fracture of the radial head; symptomatic sequelae after radial head resection; revision following failed radial head arthroplasty.	The WMT Metallic Radial Head Implants are intended for: replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and or proximal radio-ulnar joint with: joint destruction and or subluxation visible on x-ray and or resistance to conservative treatment; primary replacement after fracture of the radial head; symptomatic sequelae after radial head resection; revision following failed radial head arthroplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Mr. Albert N. Santilli
President
KAPP Surgical Instrument Company, Inc.
4919 Warrensville Center Rd.
Warrensville Heights, Ohio 44128

Re: K030237
Trade/Device Name: KAPP Custom Radial Head Elbow Implant
Regulation Number: 21 CFR 888. 3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: June 6, 2003
Received: June 11, 2003

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 (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) 594-4639. 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 may be obtained 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,

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

Enclosure

Attachment 3 – Statement of Indications for Use

510(k) Number: K030237

Device Name: KAPP Surgical Instrument, Inc. Radial Head Elbow Implant

Intended Use / Indications for Use:

The KAPP Radial Elbow Implant is intended to be used for: replacement of the proximal end of the radius:

Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and or proximal radio-ulnar joint with either joint destruction or subluxation visible on x-ray and or resistance to conservative treatment;

Primary replacement after fracture of the radial head;

Symptomatic sequelae after radial head resection;

Revision following failed radial head arthroplasty

The device is intended for custom single use with bone cement

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K030237

Prescription Use Yes
(per 21 CFR 801.109)

OR

Over the Counter Use No
Optional Format 1-2-96