K040497

JAN 26 2005

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: February 25, 2004

Applicant: Aptis Medical, LLC
5 River Hill Road
Louisville, KY 40207

Device Name:	Wrist joint ulnar (hemi-wrist) prosthesis
Device Trade Name:	Distal Radio-Ulnar Joint Implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3810
Product Code:	87 KXE
Predicate Device:	WMT Modular Ulnar Head, Wright Medical Technology, Inc.
Owner Operator Number:	9054354

Device Description:

The ulnar head implant like the predicate device includes various sizes of implants and surgical instruments. The implant allows for replacement of the distal ulnar head.

Indications for Use:

Aptis Medical Distal Radio Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
  - Pain and weakness of the wrist joint not improved by non-operative treatment
  - Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
  - Failed ulnar head resection; eg. Darrach resection

- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Wright Medical Technologies Modular Ulnar Head Implant.

Regulatory Class: II
Product Code: 87 KXE

Table 1. Comparison of Aptis and WMT ulnar head.

Item	*Aptis Product*	*Wright Medical Technologies*
Product Name	Distal Radioulnar Joint Implant	WMT Modular Ulnar Head Implant
Use	Single use	Single use
Fixation	stem in intramedulary canal, screw fixation to the distal radius	stem in intramedulary canal
Constraint	Semi constrained	non constrained
Material	Co-Cr, UHMWPe, CPTi	Co-Cr, Titanium Alloy, Plasma Spray
Sizes	2 sizes, 1, 2	8 heads, 6 stems
Indications for use	Aptis Medical Distal Radio Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty: Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings: Pain and weakness of the wrist joint not improved by non-operative treatment Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint Failed ulnar head resection; eg. Darrach resection Primary replacement after fracture of the ulnar head or neck. Revision following failed ulnar head arthroplasty.	WMT Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty: Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings: Pain and weakness of the wrist joint not improved by non-operative treatment Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint Failed ulnar head resection; eg. Darrach resection Primary replacement after fracture of the ulnar head or neck. Revision following failed ulnar head arthroplasty

Similarities of the Aptis Medical, LLC and WMT Modular Ulnar Head Implant include:

Both devices are: intended for single use only; intended for surgical implantation longer than 30 days; placed into the intramedullary canal of the distal ulna; made of industry standard materials; comparable in size; and have the same indications for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2005

Aptis Medical, LLC
C/o Ms. Louise M. Focht
P.O. Box 249
Del Mar, California 92014

Re: K040497
Trade/Device Name: Distal Radio-Ulnar Joint Implant
Regulation Numbers: 21 CFR 888.3810
Regulation Names: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Product Code: KXE
Dated: November 22, 2004
Received: November 23, 2004

Dear Ms. Focht:

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 (240) 276-0120. 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,

for Mark N. Melkerson

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

Indications for Use

510(k) Number (if known): K040497

Device Name: Distal Radio-Ulnar Joint Implant

Indications for Use:

Aptis Medical Distal Radio Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
- Pain and weakness of the wrist joint not improved by non-operative treatment
- Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
- Failed ulnar head resection; eg. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

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)

for Mark N Melkerson

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

510(k) Number K040497