K030037

p. 1/2

Special 510(k) Notification - Modification to the Universal Total Wrist System - Page 1

ADMINISTRATIVE INFORMATION

FEB 0 5 2003

Manufacturer Name:	Kinetikos Medical, Inc. 6005 Hidden Valley Road Carlsbad, CA 92009 Telephone (858) 558 2233 FAX (858) 558 0838
Official Contact	John Spampinato
Representative	John Spampinato, V. P., Quality Assurance Kinetikos Medical, Inc. 6005 Hidden Valley Road Carlsbad, CA 92009 Telephone (858) 558 2233 # 406 FAX (858) 558 0838

DEVICE NAME

Classification Name:	Wrist joint metal/polymer semi-constrained cemented Prosthesis
Trade/Proprietary Name:	Universal Total Wrist System
Common Name:	Wrist Prosthesis

PREDICATE DEVICE INFORMATION

The principal predicate device for this modification is the Kinetikos Medical Universal Total Wrist System -sizes Small, Medium and Large- originally cleared by FDA on June 6, 1996 under K961051, and modified system version cleared May 03, 2002 under K020554.

PACKAGING/LABELING/PRODUCT INFORMATION

Packaging and labeling of the device will be the same as that of the predicate Universal Total Wrist. The device will continue to be indicated for cemented use only. Samples of a package label, product brochure and the surgical technique manual with draft changes in product illustrations, are shown in Exhibit II.

INTENDED USE

The *Extra Small* KMI Universal Total Wrist implant is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, trauma-induced osteoarthritis of the radial/carpal joint. To replace functionality of the joint due to deformity or elements stated above. The Universal Total Wrist is intended for cemented use.

Special 510(k) Notification - Modification to the Universal Total Wrist System - Page 2

SYSTEM DESCRIPTION

The KMI Universal Total Wrist (UTW) System (both predicate and *extra small*) consists of the following components: the radial implant, the carpal plate implant, the carpal polymer component, and two bone screws. The system will now be offered in 4 (four) sizes: 'extra small', 'small', 'medium' and 'large'), each with 3 (three) matching polymer component sizes, which are available in varying thicknesses (height); standard, +1 and + 2. It is constructed of materials that have a long clinical history of proven acceptance and performance. This system is intended for use with cement and will be promoted as such in the UTW Surgical Protocol. Engineering drawings of the new size (extra small) and predicate UTW (small) components are shown in Exhibit III.

EQIVALENCE TO MARKETED PRODUCT

The size *extra small* has the following similarities to the predicate UTW implants which previously received 510(k) concurrence:

- -identical design
- -identical materials
- -identical operating principle
- -is packaged and sterilized using identical materials and processes

Its one distinct difference is that the size extra small is 9% smaller than the size small. In summary, the extra small Universal Total Wrist System described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2003

Mr. John Spampinato
V.P., Quality Assurance
Kinetikos Medical, Inc.
6005 Hidden Valley Road, Suite 180
Carlsbad, California 92009

Re: K030037
Trade/Device Name: Universal Total Wrist System
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: December 31, 2002
Received: January 6, 2003

Dear Mr. Spampinato:

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,

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

K030037

Special 510(k) Notification - Modification to the Universal Total Wrist System

Device Name: Universal Total Wrist System

Indications for Use:

Indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, trauma-induced osteoarthritis of the radial/carpal joint. To replace functionality of the joint due to deformity or elements stated above. The Universal Total Wrist is intended for cemented use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONITNUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use_____

for Mark N Milhous

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

510(k) Number K030037