K032806

APR 1 6 2004

APPENDIX I SUMMARY OF SAFETY AND EFFECTIVENESS

For

Katalyst Radial Head Implant

1. **Submitter:**
Kinetikos Medical, Inc.
6005 Hidden Valley Rd. Suite 180
Carlsbad, CA 92009

Contact Person:
John G. Spampinato
V.P., Quality Assurance
Kinetikos Medical, Inc.
6005 Hidden Valley Road Suite 180
Carlsbad, CA 92009
(760) 448 1706
FAX (760) 448 1739

Date Prepared: September 08, 2003

2. **Trade Name:** Katalyst Radial Head Implant
Common Name: Radial Head Implant
Classification Name: Orthopedic Elbow Implant

3. **Predicate or legally marketed devices which are substantially equivalent**

-Avanta *R Head Recon* Radial Implant System
-Tornier *BiPolar* Radial Head Prosthesis
-Biomet *Liverpool* Radial Head Replacement
-Wright Medical *Evolve* Modular Radial Head

4. **Description of Device**

The KMI Katalyst Radial Head implant is intended for use in radial head replacement arthroplasty. The system consists of modular stem and head components to accommodate variations in human anatomy. The design incorporates an adjustable stem length capability to allow stem length adjustment in-sito.

Materials: -Cobalt Chrome, per ASTM F75 -UHMWPE per ASTM 648-00
-Stainless Steel BioDur 108 Alloy per ASTM F2229

Function: The system functions as a replacement for the proximal radial head.

5. **Intended Use**

The KMI Katalyst Radial Head Implant is generally indicated for radial head replacement arthroplasty.

Use of the implant is contraindicated in those cases where complete avascular necrosis has rendered bone stock inadequate.

6. **Comparison of technological characteristics of the device to predicate and legally marketed devices:**

There are no significant differences between the KMI Katalyst Radial Head Implant and other radial head replacement systems currently being marketed which would adversely affect the use of the product. The KMI Katalyst Radial Head Implant employs the same materials and basic mechanical features as the predicate, legally marketed devices specified in section I in that the essential configuration consists of multiple size heads and stems to facilitate modularity that will accommodate a broad spectrum of patient anatomies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2004

Mr. John G. Spampinato
Vice President, Quality Assurance
Kinetikos Medical, Inc.
6005 Hidden Valley Road, Suite 180
Carlsbad, California 92009

Re: K032806
Trade/Device Name: Katalyst Radial Head
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: January 30, 2004
Received: February 9, 2004

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 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): K032806

Device Name: Katalyst Radial Head

Indications For Use:

The KMI Katalyst Radial Head system is generally indicated for use in radial head replacement arthroplasty.

Use of the implant is contraindicated in those cases where complete vascular necrosis had rendered bone stock inadequate.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K032806