K990094

2/18/99

KINETIKOS MEDICAL KMI INCORPORATED

"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."

I. Summary of Safety and Effectiveness for the KMI™ Wrist Fusion System

1. **Submitter's name, address, telephone and fax number:**
Kinetikos Medical Inc.
4115 Sorrento Valley Road
San Diego, CA 92121
Telephone: 619-558-2233 FAX: 619-558-0838

Contact Person: Michael Collins, Director of Engineering

Date Summary Prepared: January 7, 1999

2. **Name of Device:**
Proprietary Name: KMI Wrist Fusion System
Common/Usual Name: Plate, fixation, bone
Classification Name: Plate, fixation, bone

3. **Predicate Device:** Synthes Titanium Small Reconstruction Plate-K915818, and Synthes 3.5 mm Dynamic Compression Plate-a Preamendment device

4. **Description of Device:**
The KMI Wrist Fusion System consists of a rigid bar measuring 77.47 mm in length with holes to accommodate specific screws and the screws, both manufactured of 316L stainless steel.

5. **Intended Use:** KMI Wrist Fusion System is intended for wrist arthrodesis, providing fixation of small bones such as the radius and carpal bones and indicated for use in patients suffering pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed wrist fusions, segmental bone loss, or rheumatoid arthritis, while the Synthes Titanium Small Reconstruction Plate is intended for fixation of small bones such as the radius, ulna and fibula. These intended uses are substantially equivalent and do not affect safety or effectiveness.

6. **Technological Characteristics:** The Synthes Titanium Small Reconstruction Plates (K915818) are metal plates with holes for fixation of fractures of small bones and the KMI Wrist Fusion System is a metal plate with holes for wrist arthrodesis, providing fixation of small bones. The only difference is that the KMI System is manufactured of 316L stainless steel. The Synthes preamendment 3.5 mm Dynamic Compression Plate is manufactured of 316L stainless steel and consists of a metal plate with holes. There are no technological characteristics that raise new issues of safety or effectiveness.

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7. **Summary of Performance Date:** Not applicable.

8. **Conclusions Drawn from Nonclinical and Clinical Tests:** Not applicable.

4115 SORRENTO VALLEY BLVD., SAN DIEGO, CALIFORNIA 92121 TELEPHONE: (619)558-2233 FACSIMILE: (619)558-0838

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Michael Collins, M.S.
Director of Engineering
Kinetikos Medical, Inc. (KMI)
4115 Sorrento Valley Boulevard
San Diego, California 92121

Re: K990094
Trade Name: KMI Wrist Fusion System
Regulatory Class: II
Product Codes: HRS and HWC
Dated: January 7, 1999
Received: January 12, 1999

Dear Mr. Collins:

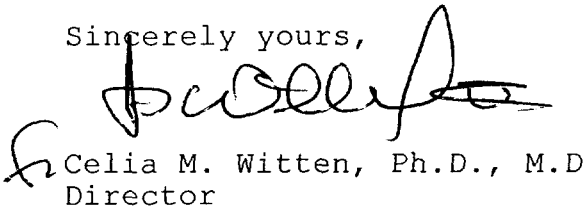
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

KINETIKOS MEDICAL
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510(k) KMI™ Wrist Fusion System
Kinetikos Medical Inc., San Diego, CA
January 8, 1999

No 510(k) Number has been issued.

Device Name: KMI™ Wrist Fusion System

Indications for Use:

The KMI Wrist Fusion System is indicated for use in patients suffering pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed wrist fusions, segmental bone loss, or rheumatoid arthritis.

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use____

(Per 21 CFR 801.109) (Optional format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990094

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