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Special 510(k) Notification - Modification to the Great Toe Implant System - Page 1

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Kinetikos Medical, Inc. 4115 Sorrento Valley Blvd. San Diego, CA 92121 Telephone (858) 558 2233 FAX (858) 558 0838
Official Contact	John Spampinato
Representative	John Spampinato, Quality Assurance Manager Kinetikos Medical, Inc. 4115 Sorrento Valley Blvd. San Diego, CA 92121 Telephone (858) 558 2233 # 406 FAX (858) 558 0838

DEVICE NAME

Classification Name:	Toe joint, phalangeal, (hemi toe) polymer prosthesis 888.3730
Trade/Proprietary Name:	K2 Hemi Toe Implant System
Common Name:	Great Toe Prosthesis

PREDICATE DEVICE INFORMATION

The principal predicate devices for this modification is the Harmos Orthodpedic, Inc., Great Toe Implant System - originally cleared by FDA on March 12, 2002 under K014164, and the Futura Biomedical Hemi Toe implant cleared by FDA on June 20, 1997 under K971047, referenced in this submission owing to its titanium plasma coating, the removal of the spike features and various dimensional changes on the K2 Great Toe Implant.

PACKAGING/LABELING/PRODUCT INFORMATION

Packaging and labeling of the device will be the same as that of the predicate Great Toe Implant. The device will continue to be indicated for press-fit 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.

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INTENDED USE

The Great Toe Implant System is indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions; Hallux valgus, hallux rigidus and an unstable or painful Metatarsal / phalangeal (MTP) joint.

SYSTEM DESCRIPTION

The KMI Great Toe Implant System consists of 4 (four) sizes of toe implants. The implants will now be plasma coated. It is constructed of materials that have a long clinical history of proven acceptance and performance. This system is intended for press fit use only and will be promoted as such in the Surgical Protocol 81-0065. Engineering drawings of the implant is shown in Exhibit III.

EQIVALENCE TO MARKETED PRODUCT

The K2 Great Toe implant has the following similarities to the predicate Great Toe implants which previously received 510(k) concurrence:

-identical design (with the exception of the elimination of the spike features)
-identical operating principle / surgical protocol
-is packaged and sterilized using identical materials and processes

The primary distinct difference is the addition of a titanium plasma coating identical to coatings used in cleared, competitive products. In summary, the extra small K2 Hemi Toe Implant 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

DEC 1 2 2002

Mr. John Spampinato
Quality Assurance Manager
Kinetikos Medical, Inc.
4115 Sorrento Valley Boulevard
San Diego, California 92121

Re: K023770
Trade/Device Name: K2 Hemi Great Toe Implant System
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint, phalangeal (hemi-toe), polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: November 8, 2002
Received: November 12, 2002

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.

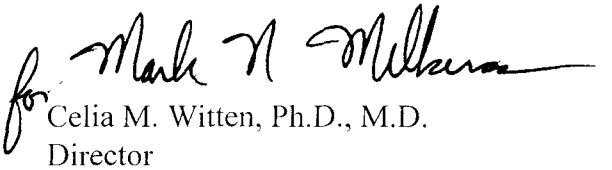
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. 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" (21CFR Part 807.97). 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

K023770

Special 510(k) Notification - Modification to the Great Toe Implant System

Device Name: K2 Hemi Great Toe Implant System

Indications for Use:

The K2 Hemi Great Toe Implant System is indicated for use in the treatment of patients with inflammatory arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head, along with the following clinical conditions; Hallux valgus, hallux rigidus and an unstable or painful MTP joint.

(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 Melkerson

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

510(k) Number K023770