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APPENDIX I SUMMARY OF SAFETY AND EFFECTIVENESS

For

MBA_{Resorb} Implant

1. Submitter:
Kinetikos Medical, Inc.
6005 Hidden Valley Rd. Suite 180
Carlsbad, CA 92011

Contact Person:
John G. Spampinato, V. P., Q.A
Kinetikos Medical, Inc.
6005 Hidden Valley Road Suite 180
Carlsbad, CA 92011
(760) 448 1706 FAX (760) 448 1739

Date Prepared: Aug 15, 2005

2. Trade Name: MBA_{Resorb} Implant
Common Name: Subtalar Maxwell-Brancheau Arthroereisis Implant
Classification Name: Orthopedic Foot Implant

3. Predicate or legally marketed devices which are substantially equivalent
-KMI Subtalar MBA Orthopedic Foot Implant (K960692 cleared Jul 23, 1996)
-Linvatec BioScrew Absorbable Interference Screw (K973758 cleared Feb 27, 1998)

4. Description of Device

The MBA_{Resorb} Implant consists of a soft-threaded implant designed to be inserted between the posterior and middle facets of the subtalar joint and corresponding instrumentation to facilitate insertion. The design differs from the predicate Subtalar MBA device only in that the material is reabsorbed into the body.

Materials: Poly L-Lactide (PLLA)
Shelf Life: This product will be labeled with a shelf life of 1 (one) year
Function: The system functions as a temporary, supplemental support to primary interventions in the treatment of flat foot.

5. Intended Use The MBA_{Resorb} Implant is indicated as an internal support to primary surgical interventions in the treatment of flat foot, providing structural support at minimum during the first three months of healing[1].

Use of this implant is contraindicated for use in patients with the following conditions:

- Active local infection / any evidence of infection
- Allergic reaction to foreign bodies
- Poor or insufficient bone stock
- The presence of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient
- Other conditions that may place the patient at risk (physiologically)

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

There are no significant differences between the MBA_{Resorb} Implant and other bioresrobable systems currently being marketed which would adversely affect the use of the product. The MBA_{Resorb} Implant employs the same basic mechanical features as the predicate, legally marketed device specified in section I, but the material is reabsorbed by the body. The poly l–lactic acid material has been in use in a variety of other implant device applications for over 10 years.

1 = Soft Tissue Procedures, *Foot and Ankle Clinics*, Volume 8, Number 3, (503-520) Sept 2003
David F. Sitler, MD, S. Josh Bell, MD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Mr. John G. Spampinato
Vice President, Quality Assurance
Kinetikos Medical, Incorporated
6005 Hidden Valley Road, Suite 180
Carlsbad, California 92011

Re: K051611
Trade/Device Name: MBAResorb Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MBJ, MJW
Dated: June 14, 2005
Received: June 17, 2005

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 (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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting 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): K051611

Device Name: Kinetikos Medical MBA_{Resorb} Implant

Indications For Use:

The MBA_{Resorb} Implant is indicated as an internal support to primary surgical interventions in the treatment of flat foot, providing structural support at minimum during the first three months of healing.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K051611