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Confidential

FDA Notification of: **Summary of Safety and Effectiveness Information**
Product: Subtalar MBA System™

Summary of Safety and Effectiveness Information

For Release Upon Request Only

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact:

Company: KMI (Kinetikos Medical Inc.)
3950 Sorrento Valley Blvd
San Diego, Ca 92110

Contact: Regulatory Affairs Department
KMI
3950 Sorrento Valley Blvd
San Diego, Ca 92110
(619) 558-2233

Establishment Registration Number: 2028840

Classification Name: Smooth or Threaded Bone Stabilization Device

Common Used Name: Subtalar Arthorisis Implant

Trade Proprietary Name: Subtalar MBA System™

The FDA has classified similar products as a Class II device by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel at Section 888-304. The product code generally refereed to is HWC (**Product Code: HWC**) , and KMI submits this application under this designation.

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Performance Standards:

No performance standards applicable to the Subtalar MBA implant have been established by the FDA. However, the titanium alloy 6AL-4V ELI alloy used to manufacture the KMI implant meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F136-84). Additionally, the titanium alloy used meets the chemical and mechanical requirements of the voluntary standards established by the American Society for Testing and Materials (ASTM 136-84, B 800-74).

Package and Labeling:

Draft Package labeling has been developed and enclosed in Section 2 attachments. A draft package insert has also been developed and enclosed in Section 2 for your review and consideration.

System Description:

The KMI Subtalar MBA System™ will be offered in Ti-6Al-4V ELI. It will be available in a range of diameters and will be cannulated for precise location of the implant. Initially, a range of four diameters will be made available in 15mm lengths. All four diameters (6,8,10, and 12mm) are implantable using a standard (e.g. American Orthopedic) hexhead screwdriver, which is cannulated at center.

Indications for Use:

The KMI Subtalar MBA System™ will be used on indications that are common with presently marketed devices. The primary indications for use of the Subtalar MBA System™ is as a spacer for stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

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Substantial Equivalent Devices:

This product is substantially equivalent in design, composition and/or function to another orthopedic implant device manufactured and approved for market.

Wright Medical: **K792670**

The KMI Subtalar MBA System™ meets the ASTM standards (ASTM B348-83, F136-84, F67-88) for material and design of implants for medical application. The implant serves to function as the device listed above, and will have a higher loading capacity because it is made from titanium rather than polyethylene like the devices from many other orthopaedic companies being offered in the market.

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Instrumentation:

KMI Subtalar MBA System™ instrumentation used for the preparation and insertion of the Subtalar implant is considered to be general orthopaedic instrumentation. The system includes standard manual orthopaedic surgical instruments of the appropriate size and type. All Subtalar MBA System instruments are manufactured from stainless steel meeting ASTM F899-84 standards.

Product Sterilization:

KMI will supply all instruments and implants **Non-Sterile**. Non-Sterile implants are packaged in "clean only" condition. The labeling of the implants and instruments clearly indicates their sterility status. The package insert contains a sterilization/re-sterilization guideline.

Summary:

Substantial Equivalence for the KMI Subtalar MBA System™ may be found in comparison with devices from a number of manufactures. Subtalar joint implant systems in general have been used for many years, and the clinical performance is well known and documented in the body of this submission.

Another measure of the Safety and Effectiveness of a medical device is how it performs in long term use. The basic design concept of stabilizing the subtalar joint for correction of flatfeet and associated midfoot adjustments has over 20 years of clinical evaluation. Uses, Indications, limitations and surgical techniques are well understood. Standardized manufacturing methods, design practices, material selections and testing techniques are known and represented within the guidelines of this submittal.

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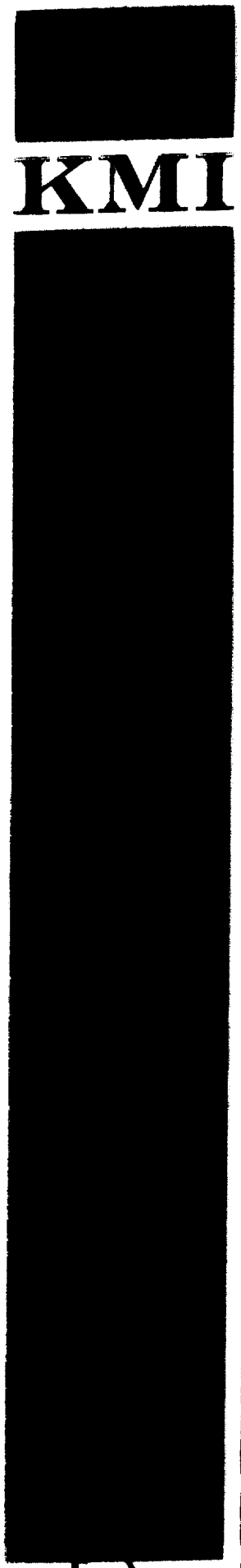
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Draft Package Label:

Draft Package Label

KMI Subtalar MBA Implant
Catalog #05-0110

Non-sterile

Quantity: 1

Diameter: 10 mm
Length: 15 mm

Material: Titanium Alloy (6AL-4V, ELI)

Manufactured For: KMI
3950 Sorrento Valley Blvd.
San Diego, Ca 92121

Warning: Federal Law (USA) restricts this product to sale by or on the order of a physician.
Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PN Xs Rev A KMI, 1996 Subtalar MBA System™

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Product: Subtalar MBA System™

Draft Package Insert:

Package Insert for Subtalar MBA System™

Caution:

U.S. Federal Law restricts this product to sale on or by the order of a physician.

1. The surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of metallic surgical implants.
2. The patient should be adequately instructed. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the subtalar implant, and that physical activity and full weight bearing have been implicated in premature failure of similar devices. The patient should be made aware that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing.
3. Removal of the implant after position correction or healing. Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young active patients. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid mis-alignment. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant, thus eliminating the risks involved in a second surgery.
4. Until firm re-alignment (confirmed by clinical and radiographic examination) is established, the patient should employ adequate external support and restrict physical activities which would place excessive stresses upon the subtalar implant or allow movement and delay or prevent healing and re-alignment to occur.
5. Periodic follow-up with image evaluation is critical. Even when the re-alignment and stabilization is complete, forces continue to be placed on the implant, and failure may occur.

Safety Precautions:

1. Correct selection of the implant size is extremely important. The potential for satisfactory stabilization is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal stabilization devices cannot withstand activity levels equal to those placed on normal, healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing

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Draft Package Insert Cont'd:

2. Implants can break when subjected to the increased loading associated with delayed stabilization or re-alignment. Internal stabilization appliances are load sharing devices which are used until normal healing and alignment occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of stabilization, loads produced by weight bearing and activity levels will dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early fatigue failure (Patients should be fully informed of risks of implant failure).

3. Correct handling of the implant is extremely important. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

4. Mixing metals can cause corrosion. Dissimilar metals in contact, such as titanium implants used with stainless steel bone plates, accelerate the corrosion process of stainless steel and rapid attack occurs. The presence of corrosion process of stainless steel and rapid attack occurs. The presence of corrosion accelerates fatigue fracture of the implant. Internal stabilization and/or fixation devices, such as implants, plates and screws which come in contact, must be made from like or compatible metals.

5. Surgical implants must never be reused. An ex-planted implant should never be re-implanted.

SPECIFIC INDICATIONS FOR USE:
The Subtalar MBA System is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Severely pronated foot
Walking intemperance
Calcaneal stance position greater than 5°
Manually correctable deformity
Mid-tarsal breech (arch pain)
Forefoot varus greater than 10°

The Subtalar impalnt is contraindicated for use in patients with the following conditions:

Active local infection (Any evidence of infection)
Metal sensitivity or allergic reaction to foreign bodies.
Other conditions that may place the patient at risk (Physiologically)
When quality of bone stock prevents secure seating of the implant
The presense of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient

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Draft Package Insert Cont'd:

Possible Adverse Effects
The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal stabilization devices. General surgical risks should be explained to the patient prior to surgery.

1. Infection.
2. Pain, discomfort, or abnormal sensations due to presence of the implant
3. Metal sensitivity, or allergic reaction to a foreign body
4. Migration of the implant, loosening of the implant
5. Delayed correction in alignment
6. Decrease in bone density due to stress shielding
7. Bursitis

Possible Risks and Complications:
1. **Implant improperly positioned.**
2. **Failure to fully ~~re~~implant.**
3. **Failure to appropriately stabilize or re-align the subtalar joint.**
4. **Failure to correct the deformity.**

Packaging:
Each of the KMI Subtalar Implants should be received in an intact package. Damaged packages or products should not be used and should be returned to KMI.

Sterilization:
Unless supplied sterile and clearly labeled as such, all Subtalar implants must be steam autoclaved prior to use in surgery. KMI Subtalar implants and instruments may be steam sterilized by the hospital using the following process parameters:

Method:	Steam
Cycle:	Gravity
Temperature:	270 F (132 C)
Exposure Time:	30 minutes

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Immediately re-sterilize all implants and instruments removed from the surgical field before handling. Never re-use surgical impalnts.

PN XXXXXXXXXX, Rev A Manufactured & Distributed by KMI, Inc.
KMI, 1996 3950 Sorrento Valley Blvd San Diego, CA 92121

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Packaging:

All packaging will be of a sufficient design and material quality to provide protection from physical damage during transportation and storage. Typical packaging used for such applications are medical grade peel packs, blister packs, pouches, boxes with foam compartments, clear plastic tubes with end caps and fiberboard shippers and cartons.

The packaging offered is equivalent to that which is used with the predicate devices listed within this document, and in most cases is supplied by the same manufacturers that supply major orthopaedic companies.

Currently, KMI is considering medical grade peel packs and/or plastic tubes for the individual packaging of the Subtalar implants. The package or tube will be sealed which will provide for the integrity and security of the product. The implants will be provided non-sterile and labeled as such.

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Promotional Material:

This system's promotional material has not been developed. However, all promotional material will be developed within the guidelines set fourth by the FDA as they pertain to these products

KMI's Subtalar MBA System™ promotional material will be similar and in most cases more informative then that material which is supplied with the predicate devices listed within this notification

A draft protocol and catalog listing is provided on the next page for reference, however these items are currently under review and may change prior to distribution of product.

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