

COPY

Confidential

MAR 25 1996

K960537

FDA Notification of:

Summary of Safety and Effectiveness Information  
Product: K2 Bone Screw 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 Fixation  
Fastener

**Common Used Name:** Bone Screw

**Trade Proprietary Name:** K2 Bone Screw 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 referred to is HWC ( **Product Code: HWC** ), and KMI submits this application under this designation.

**FDA Notification of:**

**Summary of Safety and Effectiveness Information  
Product: K2 Bone Screw System™**

**Performance Standards:**

No performance standards applicable to the Bone Screw have been established by the FDA. However, the titanium alloy 6AL-4V ELI alloy used to manufacture the KMI screws meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F136-84).

**Package and Labeling:**

Package labeling has been developed to industry standards. Packaging is also standard commercially available type quality and is stored in a fashion which prevents damage to the container or package the device is in.

**System Description:**

The KMI K2 Bone Screw System™ will be offered in Ti-6Al-4V ELI. It will be available in common styles and assorted lengths for bone fracture fixation and stabilization. Initially, a range of eleven screw lengths will be made available in 2.8 mm diameter (10-30 mm), and eight screw lengths will be made available in the 2.4 mm (6-20 mm) diameter screw. Both screw types are implantable using a standard (e.g. American Orthopedic) hexhead screwdriver, which is cannulated at center.

**Indications for Use:**

The KMI K2 Bone Screw System™ will be used on indications that are common with presently marketed devices. The indications for use of the K2 Bone Screw System™ are fixation/stabilization of small bone hand or small bone forefoot fractures.

**FDA Notification of:**

**Summary of Safety and Effectiveness Information  
Product: K2 Bone Screw System™**

**Substantial Equivalent Devices:**

This product is substantially equivalent in design, composition and function to other orthopedic screws manufactured and approved for market.

|                              |                |
|------------------------------|----------------|
| <b>Ace Medical Company:</b>  | <b>K903810</b> |
| <b>Alphatec Medical:</b>     | <b>K921622</b> |
| <b>Howmedica:</b>            | <b>K931524</b> |
| <b>Aesculap:</b>             | <b>K940207</b> |
| <b>Osteomed:</b>             | <b>K924018</b> |
| <b>Zimmer:</b>               | <b>K792022</b> |
| <b>A.O. Synthes</b>          | <b>K792291</b> |
| <b>Johnson &amp; Johnson</b> | <b>K?</b>      |
| <b>ISI Manufacturing</b>     | <b>K?</b>      |

The KMI K2 Bone Screw System™ meet the ASTM standards (ASTM B348-83, F136-84, F67-88) for material and design for medical application. The bone screws are of the same thread configuration and length as offered by Ace Medical, A.O. Synthes, Zimmer, Johnson & Johnson, Alphatec and many other orthopaedic companies. The minor and major diameters as well as the head size are comparable.

**FDA Notification of:**

**Summary of Safety and Effectiveness Information**

**Product: K2 Bone Screw System™**

**Instrumentation:**

KMI K2 Bone Screw System™ instrumentation used for the preparation and insertion of the K2 Bone Screws is considered to be general orthopaedic instrumentation. The system includes standard manual orthopaedic surgical instruments of the appropriate size and type. All K2 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 K2 Bone Screw System™ may be found in comparison with devices from a number of manufactures. Bone Screw systems in general have been used for many years, and the clinical performance is well known and documented.

Another measure of the Safety and Effectiveness of a medical device is how it performs in long term use. The basic design concept of bone screws for use in the fixation and stabilization of fractures has had over 75 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.