JUN - 6 1996

KINETIKOS MEDICAL
KMI
INCORPORATED

K961051

Confidential

FDA Notification of: **Summary of Safety and Effectiveness Information**
Product: Universal Total Wrist™ 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 92121

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

Establishment Registration Number: 2028840

Classification Name: Wrist Prosthesis (metal/plastic/metal semi-constrained), 87JWJ

Common Used Name: Wrist Prosthesis

Trade Proprietary Name: Universal Total Wrist™ 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 87JWJ (**Product Code: JWJ**) , and KMI submits this application under this designation.

KINETIKOS MEDICAL
KMI
INCORPORATED

Confidential

FDA Notification of: **Summary of Safety and Effectiveness Information**
Product: Universal Total Wrist™ System

Performance Standards:

No performance standards applicable to semi-constrained wrist implant have been established by the FDA. However, the titanium alloy 6AL-4V ELI alloy used to manufacture the carpal plate implant meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F136-84). Additionally, the CrCoMo used in the radial implant per ASTM F-75-87 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 will be offered in three sizes (small, medium, and large) with the poly bearing implant also offered in three sizes to match the carpal plate implants. The Universal total Wrist implant is constructed of materials that have a long clinical history of proven acceptance and performance. This system is intended for use with cement and will be promoted as such in the UTW surgical protocol

Indications for Use:

The KMI Universal Total Wrist™ System is indicated for intractable pain resulting from traumatic arthritis, osteo arthritis, rheumatoid arthritis, trauma induced osteo arthritis of the radial / Carpal joint. To replace functionality of the joint due to deformity or elements stated above.

Substantial Equivalent Devices:

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

Protek Meuli Wrist:	**K ?**
Howmedica AMC Wrist:	**K ?**
Depuy Bi-Axial Wrist:	**K ?**

KINETIKOS MEDICAL
KMI
INCORPORATED

Confidential

FDA Notification of: **Summary of Safety and Effectiveness Information**
Product: Universal Total Wrist™ System

Instrumentation:

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

Product Sterilization:

KMI will supply all implants **Sterile**. The product will be sterilized by Gamma radiation. The minimum dosage will be 25Kgy with a maximum of 45Kgy. Validation of the product will be made to ensure a sterile assurance level (SAL) of 10-6 per AMMI standard guidelines.

Summary:

Substantial Equivalence for the KMI Universal Total Wrist™ system may be found in comparison with devices from a number of manufactures. Wrist 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 replacing the weakened bone anatomy of the wrist for relief from traumatic arthritis, osteo arthritis, and rheumatoid arthritis 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.

3950 SORRENTO VALLEY BLVD., SAN DIEGO, CALIFORNIA 92121 TELEPHONE: (619)558-2233 FACSIMILE: (619)558-0838