

510(k) SUMMARY
Skeletal Dynamics Inc.'s
Distal Humerus Plating System

Submitter

Skeletal Dynamics, Inc.
7300 N. Kendall Drive
Suite 400
Miami, FL 33156
Phone: 305-596-7585 ext.7121
Facsimile: 305-596-7591
Contact Person: Alexandra Rodriguez
Date Prepared: January 13, 2022

Name and Classification

Trade Name: Distal Humerus Plating System
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Classification Number: 21 CFR §888.3030
Regulatory Class: Class II
Product Code: HRS

Predicate Devices

Distal Humerus Plating System, K200367

Device Description

The Skeletal Dynamics Inc's Distal Humerus Plating System consists of five titanium bone plates in different shapes (medial direct, lateral direct, lateral helical, lateral capitellar, and supracondylar), in multiple lengths, and in left and right configurations to address distal humerus fractures. The plates are made of medical grade titanium alloy. The system also includes 2.7mm, 3.5mm and 4.5mm locking and compression titanium alloy screws and 3.0mm polyaxial Cobalt Chrome locking screws which are provided in various lengths. The System is being modified to include additional lengths of existing screw options and new 3.5mm and 4.5mm locking and compression Titanium Alloy Screws. Additionally, minor modifications have been made to the plates to accept the new screws above mentioned. Also included in the system is specialized instrumentation. The System is provided non-sterile for sterilization in the user facility.

The Distal Humerus Plating System is comprised of:

- Titanium alloy plates, screws, and fasteners
- CoCr Cannulated Polyaxial Locking Screws (PLS)
- Stainless steel K-wires (for provisional fixation; not for implantation)
- System specific instrumentation

Indications for Use

The Skeletal Dynamics Inc's Distal Humerus Plating System is indicated for intra-articular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

Summary of Technological Characteristics

The substantial equivalence of the Distal Humerus Plating System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging and does not present any new issues of safety or effectiveness.

Performance Testing

Engineering analysis and mechanical testing demonstrated that the Skeletal Dynamics Inc's Distal Humerus Plating System is equivalent to predicate devices currently marketed. Static testing, which established equivalency included ASTM-F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws*. Therefore, the subject device is as safe and effective as the legally marketed predicate device.

Conclusions

The Skeletal Dynamics Inc's Distal Humerus Plating System is substantially equivalent to the predicate device identified in this premarket notification.