



510(k) SUMMARY

Ulnar Shortening Plating System

Submitter

Skeletal Dynamics, Inc.
7300 N. Kendall Drive, Suite 400
Miami, FL 33156
Phone: 305-596-7585
Facsimile: 305-596-7591
Contact Person: Diana Taylor
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Name and Classification:

Name: Skeletal Dynamics Ulnar Shortening Plating System
Common Name: Screw, Fixation, Bone
Classification: 21 CFR §888.3030
Regulatory Class: Class II
Product Code(s): HRS

Predicate Devices:

Primary Predicate Device: Medartis APTUS 2.5 Ulna Shortening Plate (K141232, 06/23/2014)
Additional Predicate Device: Medartis APTUS 2.5 TriLock Plate (K103332, 01/24/2011)

Device Description: The Skeletal Dynamics Ulnar Shortening Plating System consists of Distal Ulnar Shortening Plates with left and right configurations in two lengths and Proximal Ulnar Shortening Plates in two lengths. The Ulnar Shortening Plates are from medical grade Titanium Alloy (ASTM F136). Included within the Ulnar Shortening Plating System Set are 3.5mm cortical locking and non-locking bone screws as well as 2.3mm and 2.7mm locking and non-locking pegs from medical grade Titanium Alloy (ASTM F136) for fixation and class 1 surgical instrumentation.

Indications for Use: The Skeletal Dynamics Ulnar Shortening Plating System is indicated for fractures and osteotomies, in particular for the ulna.

Summary of Technological Characteristics: The substantial equivalence of the modifications to the Headless Compression Screw to the cleared predicate system is demonstrated by their identical indications for use, materials, design (fundamental scientific technology) and performance and does not present any new issues of safety or effectiveness.

Performance Testing: Static and dynamic bend strength was submitted with input from ASTM F382, Standard Specification and Test Method for Metallic Bone Plates ASTM F2193, Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System and ASTM F1541, Standard Specification and Test Methods for External Fixation Device. The performance test data as well as engineering analysis provided confirms the Skeletal Dynamics Ulnar Shortening Plating System performance to be substantially equivalent to the predicate devices.

Conclusion: As confirmed within this premarket notification, the Skeletal Dynamics Ulnar Shortening Plating System is equivalent to the legally marketed predicate devices and present no new issues with safety or effectiveness.