

K955472

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ACE UPPER EXTREMITY PLATE SYSTEM

Ace Medical Company
2260 East El Segundo Blvd.
El Segundo, CA 90245
Phone (310) 615-0066

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Contact Person: Nancy Giezen
Senior Regulatory Affairs Specialist

Paul Doner
Director, Regulatory/Clinical Affairs

Proprietary Name: ACE Humerus Plates
ACE Radius Plates

Common Name: Bone Plate

Classification Name: Single / Multiple Component Metallic
Bone Fixation Appliance and
Accessories, 21 CFR 888.3030

Proposed Regulatory Class: Class II

Classification Panel: Orthopaedic Device Panel

Device Product Code: 87HRS Plate, Fixation, Bone

Device Description:

The ACE Humerus Plates and Radius Plates are anatomically contoured bone plates which are attached to the bone with cortical or cancellous bone screws. The humerus plates will offered in two configurations for both the left side and the right side. The plates are offered in three hole and five hole configurations.

The ACE Radius plates are also offered in a right and left configuration both for volar fixation and dorsal fixation. The plates are offered in a large and a small size.

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Intended Use:

The Distal Radius Plate System is designed for internal fixation of the distal radius. The distal radius plates are available in left and right volar configurations and in two sizes, small and large.

The Humerus Plate System is designed for internal fixation of the proximal humerus. The humerus plates are available in right and left configurations and in three hole and five hole length.

Cortical and cancellous bone screws are required to secure the plates to the bone. A variety of screw are available for this application in order to accommodate different fracture types and locations, bone density and surgeon preference.

Substantial Equivalence:

The ACE Humerus Plate and Radius Plate systems are considered substantially equivalent to the DePuy ORIF Small Fragment Plates and the Synthes Small Plates and Small Titanium Plates.

Performance Data:

The ACE Humerus and Radius plates were tested in static bending and compared to the Synthes (USA) and the DePuy plates. Three types of plates (proximal humerus, volar distal radius and dorsal distal radius) were tested by applying static cantilever bending forces on the shaft/buttrass interface of the plate. The ACE Plates were comparable in bending strength to the predicate device

Safety and Effectiveness:

The upper extremity plates are manufactured of a biocompatible titanium alloy, commonly used in the orthopedic industry. The plates were shown to exhibit strength characteristics comparable to the predicate device. Thirdly, no new indications have been introduced with these devices. Therefore, the ACE upper extremity plates are considered to be a safe and effective means of fracture fixation.