

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K96 3350

NAME OF FIRM:

DePuy Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

NOV 14 1996

510(K) CONTACT:

Cheryl Hastings
Manager, Clinical Affairs

TRADE NAME:

DePuy Motech PEAK Fixation System

COMMON NAME:

Bone Plate

CLASSIFICATION:

888.3030 Single/multiple component metallic bone fixation
appliance and accessories

DEVICE PRODUCT CODE:

Product code: 87 HRS

**SUBSTANTIALLY
EQUIVALENT DEVICES:**

- ▶ ACE 100° Tubular Plate
- ▶ Synthes (USA) LC-DCP Plate Set System
- ▶ Synthes (USA) 1/3 Tubular Stainless Steel Plates

INTENDED USE AND DEVICE DESCRIPTION:

The DePuy Motech PEAK Fixation System is intended for use in treating fractures of small bones such as the metacarpals, ulna, radius, humerus and metatarsals and in treating fractures of the lateral malleolus, olecranon, and intra-articular distal tibia. The system consists of 5 sizes of channeled reconstruction plates ranging from 26mm to 104mm in length, 13 sizes of 3.5mm cortical screws ranging from 16 to 30mm in length and a steplock washer. The reconstruction plates are 3mm thick and 9mm wide. All plates incorporate a tooth pattern, on one outer surface. The teeth are designed to interlock with the "tabs" on the steplock washer.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Motech PEAK Fixation System is similar in material, design and intended use to the ACE 100° Tubular Plate and the Synthes LC-DCP Plate Set System. All of these systems consist of CP Titanium bone plates and screws intended to treat fractures of small bones. The ACE plate has a length of 97mm, 8 holes, a width of approximately 9mm and a thickness of approximately 1.3mm and is intended to be used with cancellous screws with diameters of 4.0mm or less. The Synthes system contains plates with lengths from 25mm to 120mm with 2 to 10 screw holes per plate, and is designed to be used with 3.5mm cortical bone screws. The 3.5mm screws range in length from 10mm to 50mm.

Mechanical testing shows that in 4 point bending the rigidity, strength and stiffness of the DePuy Motech PEAK Fixation System channeled reconstruction plates exceed those of the ACE 100° Tubular Plate and Synthes 1/3 Tubular Stainless Steel Plates.