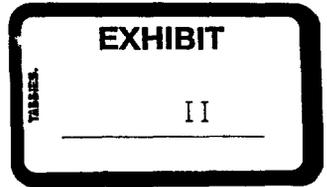


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JUN 19 1996

SUMMARY OF SAFETY AND EFFECTIVENESS



NAME OF FIRM: DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

FIRM CONTACT: Sally Foust
Clinical Research Specialist

TRADE NAME: DePuy Advantage™ Fixation Screw System

COMMON NAME: Bone Screw

CLASSIFICATION: 888.3040 Smooth or threaded metallic bone fixation fastener

DEVICE PRODUCT CODE: 87 HWC

SUBSTANTIALLY EQUIVALENT DEVICES:
Depuy M. Kurosaka™ Interference Screw
DePuy M. Kurosaka™ Fixation Screw
Arthrex Transtibial™ System

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Advantage Fixation screw is a fully threaded titanium alloy cancellous bone screw available in 7mm and 9mm diameters. Each diameter is available in six (6) lengths (15, 20, 25, 30, 35, and 40mm) in a cannulated version, and in five (5) lengths (20, 25, 30, 35, and 40mm) in a non-cannulated version. The Advantage screw has a polished satin finish, a 29 degree included angle tapered tip, a round body thread, and a radius on the socket end of the screw. Each screw has an internal hex fitting for instrument insertion during surgery.

The DePuy Advantage Fixation Screw System is intended to be used to provide interference fixation of patellar bone-tendon-bone grafts in anterior cruciate ligament (ACL) reconstruction.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Advantage Fixation Screw System screws are substantially equivalent to the DePuy M. Kurosaka Interference Screws cleared for fixation of bone-tendon-bone grafts in ACL reconstruction. All of the DePuy Advantage screws and the M. Kurosaka Interference screws are manufactured from Ti-6Al-4V alloy. All are available in 7mm and 9mm diameters in numerous lengths in cannulated and non-cannulated versions.