

K955733

NOV 18 1996

X. SUMMARY OF SAFETY AND EFFECTIVENESS**SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary**

NAME OF FIRM: DePuy Inc
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TRADE NAME: Phantom™ PLLA Interference Screw

COMMON NAME: Bone/Tendon/Bone Screw

CLASSIFICATION: Smooth or threaded bone fixation fastener; 888.3040

DEVICE PRODUCT CODE: 87 HWC

SUBSTANTIALLY EQUIVALENT DEVICES:

- BioScrew® Fixation System (Linvatec) - K933719
- M. Kurosaka Interference Screw (DePuy) - K933798
- Biologically Quiet Interference Screw (Instrument Makar) - K943249

DEVICE DESCRIPTION AND INTENDED USE:

The Phantom PLLA Interference Screw is an absorbable interference fixation screw. The DePuy DuPont Phantom™ Interference Screw is a fully threaded cancellous bone screw available in 7.0mm, 8.0mm and 9.0mm diameter sizes. Each diameter is available in either 15, 20, 25, and 30mm lengths and is offered in cannulated and non-cannulated versions.

The tip of the 9mm sized screw is tapered to a point which produces the self tapping feature of the screw. The screw is inserted by a square drive which is broached into the minor diameter of the screw body. The headless, low profile design minimizes subcutaneous surface protrusions. The threads are a symmetrical thread form designed to equally match stiffness between bone and thread. The Phantom screw is radiolucent on x-rays, but can be visualized with MRI and CAT scans.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Phantom™ Interference Screw, M. Kurosaka Interference Screw and the BioScrew® are intended to provide bone-tendon-bone patellar graft fixation, employing the same principles of graft fixation. These fixation screws provide an interference fit engaging both the drill tunnel and the bone plug of the graft. The Phantom™ Interference Screw is substantially equivalent to the M. Kurosaka Screw with respect to design and intended use and is substantially equivalent in material, design and intended use to the Bioscrew.

Both the Phantom™ Interference Screw and the Bioscrew® are manufactured from PLLA (Poly L-Lactic Acid) absorbable polymers and the M. Kurosaka/Advantage Screw is manufactured from Ti-6Al-4V alloy. All three screws are headless and fully threaded. The BioScrew® is offered in a cannulated version only. The M. Kurosaka Interference Screw and the Phantom™ Interference Screw are offered in both cannulated and non-cannulated versions.