

FEB - 6 1997

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**NAME OF FIRM:** DePuy Inc.  
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**TRADE NAME:** DePuy DuPont Phantom Suture  
Anchor

**CLASSIFICATION NAME:** Smooth or threaded metallic bone fixation fastener

**PRODUCT CODE:** ~~79-JDR~~ 87 MAI

**SUBSTANTIALLY EQUIVALENT DEVICES:**  
Zimmer Statak  
Acufex Suretac Absorbable Tack

**INTENDED USE AND DEVICE DESCRIPTION:**

The DePuy DuPont Phantom Suture Anchor is intended for use in the shoulder for soft tissue re-attachment and capsular repair, including rotator cuff repairs, Bankart lesion repairs and SLAP lesion repairs.

The Phantom Suture Anchor is a PLLA cortical screw with a flat tip and a rectangular head. Two holes run parallel to the axis of the screw. A #2 nonabsorbable polyester suture is pre-threaded sequentially through these holes with a single loop at the tip of the screw. The suture anchors are available either pre-loaded on a driver or separately. The Phantom Suture Anchors are available in diameters of either 3.5 or 4.5mm.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The DePuy DuPont Phantom Suture Anchors are substantially equivalent to the Zimmer Statak and the Acufex Suretac in that all of these devices are suture anchors which are intended for soft tissue re-attachment in the shoulder. The Phantom Suture Anchor is a resorbable anchor manufactured from PLLA. The Acufex Suretac is a resorbable tack manufactured from polyglyconate. The Zimmer Statak is non-resorbable and is manufactured from Ti-6Al-4V metal alloy. Both the Phantom suture anchors and the Stataks have a threaded design. Mechanical testing in cadaver bone showed that the pull-out loads for the Phantom Suture Anchors were comparable to the pull-out loads for the Statak anchors.