

K965175

510(k) Summary

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**Device:** Howmedica Mainstay™ Soft Tissue Anchor

The Howmedica Mainstay™ Soft Tissue Anchor is a titanium alloy self-drilling, self-tapping cancellous screw threaded device for the attachment of soft tissue to bone. The device is available in three sizes and has a proximal thru-hole for the attachment of the desired suture material. The purpose of the device is to hold, with sutures, the soft tissue against the bone for a prescribed healing period. This device is to be used for soft tissue attachment in the shoulder, ankle, foot, wrist, hand, elbow, knee and pelvis.

The 510(k) for this device K953531 was determined to be substantially equivalent on September 26, 1995. This present submission is being made to introduce an additional indication for use in soft tissue reconstruction following total hip arthroplasty. Testing was performed in accordance with that described in the FDA "Bone Anchor Devices: Guidance for Testing - April 20, 1996." Results of this testing indicated that the initial fixation strength of the Mainstay™ Soft Tissue Anchor did not differ significantly from that of the Mitek SuperAnchor when used in the same anatomic site.

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