K964953

Summary of Safety and Effectiveness
Influence, Inc.'s In-Tac Bone Anchor System
510(k) Number K964953

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This 510(k) notification is submitted by Influence, Inc., 601 Montgomery Street, Suite 845, San Francisco, California 94111. The contact person is Peter A. Bick, President and CEO.

This 510(k) notification addresses modifications to the Influence, Inc. UroTac Bone Anchor System, a staple driver (21 CFR 888.4540) cleared under K962372. The modified device will be called the In-Tac Bone Anchor System. The modifications have been implemented to improve convenience of device use, and to provide enhanced material strength. In addition, the labeling has been modified to incorporate the indication for stress urinary incontinence resulting from intrinsic sphincter deficiency, and to provide instructions for use of the device in transvaginal sling procedures.

Like the UroTac Bone Anchor System, the In-Tac Bone Anchor System is intended for soft tissue fixation to the pubic bone by means of bone anchors threaded with suture. The In-Tac Bone Anchor System is indicated for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Like the UroTac Bone Anchor System, the In-Tac Bone Anchor System consists of two components: a bone anchor, and a bone anchor inserter The In-Tac Bone Anchor System has the same overall design and technological characteristics as the configuration cleared under K962372, but implements the following changes: (1) the sutures will be provided pre-threaded for user convenience, and the retractable anchor shield will be incorporated into the disposable anchor assembly; (2) the inserter will be made from a stronger grade of stainless steel; and (3) the inserter incorporates a force measuring spring to ensure the anchors are deployed only if sufficient insertion force is applied.

All materials used in the In-Tac Bone Anchor System are commonly used in medical devices. Biocompatibility testing demonstrated that the materials are biocompatible. Bench testing demonstrated that the modifications made to the UroTac Bone Anchor System had no effect on device safety and effectiveness, and that its performance is substantially equivalent to the 510(k)-cleared configuration.

Based on the information provided, the In-Tac Bone Anchor System is substantially equivalent to the UroTac Bone Anchor System with respect to intended use, technological characteristics, and performance.