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510(k) Summary of Safety and Effectiveness
Influence, Inc.'s *In-Fast* Bone Screw System
510(k) Number K97-0292

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 & CEO.

This 510(k) notification describes a bone screw and bone screw inserter intended for soft tissue fixation to the pubic bone by means of bone screws with attached suture. The *In-Fast* Bone Screw System is indicated for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The *In-Fast* Bone Anchor System is substantially equivalent to Influence, Inc.'s *UroTac* Bone Screw System cleared under K962372. The mechanical properties and technical procedure of the two systems are almost identical. In both devices, fixation of soft tissue to bone is accomplished by a sharp tipped small diameter bone screw/anchor anchor threaded with polypropylene suture which is inserted pervaginally through soft tissue and into the pubic bone, without drilling holes or performing soft tissue dissection. The screw/anchor is loaded into an inserter which is positioned in the vagina. Pulling force is applied on the user handle to pass the screw/anchor's tip into the bone cortex. The inserter's safety lock is released and screw/anchor is inserted into the prescribed depth in the pubic bone. In the *In-Fast* system, the screw is threaded into the bone by the inserter's rotating shaft. In the *UroTac* system, the anchor is pushed into the bone by the spring-loaded inserter. A cystourethropexy procedure is then performed which is identical for both the *UroTac* and *In-Fast* systems. Alternately, a transvaginal sling procedure may be performed using the *In-Fast* which is substantially equivalent to the in situ sling technique used in conjunction with the *Vesica* Suture Anchor System (K932925, Boston Scientific Corp., by its Microvasive division, the successor-in-interest to *Vesica* Medical, Inc., formerly Vesitec).

The *Mitek GII* Anchor (K920213), used in bladder neck suspensions, and the *In-Fast* bone screw have been proven to provide substantially equivalent fixation strength. The *Questus*™ Polyester Soft Tissue Anchor System (K953264 and K963200, Wright Medical Technologies, Inc.) is also used in bladder neck suspensions and closely resembles the screw used in the *In-Fast* system.

All materials used in the *In-Fast* Bone Screw System are either commonly used in medical applications or have been proven to be biocompatible through biocompatibility testing. Bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to a 510(k) cleared device.

Based on the information provided, the *In-Fast* Bone Screw System is substantially equivalent to the *UroTac* System with respect to intended use, technological characteristics, labeling, performance and surgical procedure. Also based on the

information provided, the *In-Fast* Bone Screw System is substantially equivalent to the *Mitek GII* Anchor with respect to intended use, technological characteristics and performance; *the Vesica* Suture Anchor System with respect to intended use, technological characteristics, performance and its use in the vaginal sling procedure; and the *Questus*™ Polyester Suture Soft Tissue Anchor with respect to intended use, technological characteristics and performance.