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Influence, Inc.
637 Steiner Street
San Francisco, California 94117
Tel. 415-552-4303/Fax. 415-552-4309

K962372

510(k) SUMMARY

Prepared: June 18, 1996.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Section 807.92.

SUBMITTER

NAME	Influence, Inc.
ADDRESS	637 Steiner Street San Francisco, California 94117
TEL.#/FAX#	415-552-4303 / 415-552-4309
CONTACT	Peter A. Bick, MD President

NAME OF DEVICE *UroTac* Bone Anchor System
Consisting of:

TRADE NAME *UroTac* Bone Anchor
COMMON NAME Device for soft tissue to bone attachment.
CLASSIFICATION NAME Staple, Fixation, Bone

TRADE NAME *UroTac* Bone Anchor Inserter
COMMON NAME Instrument used to insert bone anchor in desired situs.
CLASSIFICATION NAME Surgical Instrument - Staple Driver

PREDICATE DEVICE

MITEK GII Bone Anchor (and accessories) (K920213)
MICROVASIVE (VESICA) Bone Anchor (K932925)

DESCRIPTION OF THE DEVICE

FUNCTION

Fixation of non-absorbable suture below bone surface for soft tissue fixation.

DEVICE DESIGN

Suture anchor constructed of Nitinol designed to lock into medulla of the pubic bone when pull force is applied to the suture attached to the anchor.

MATERIAL

Anchor - Nitinol
Inserter - Stainless Steel (ASTM F899-94).

INTENDED USE

The *UroTac* Bone Anchor System is intended for soft tissue fixation to the pubic bone by means of bone anchors threaded with suture. The *UroTac* Bone Anchor System is indicated for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility.

COMPARISON TO PREDICATE DEVICES

The predicate device is the Mitek GII Anchor. Equivalent features include: use in connection with bladder neck suspension procedure to accomplish soft tissue fixation to the pubic bone; insertion of anchor into pubic bone; use of an inserter to set the anchor into the pubic bone; use of Nitinol as an essential material; use of USP Class I suture; and initial fixation strengths that are substantially equivalent. Microvasive's Vesica Bone Anchor is a predicate device by virtue of the similarity of certain aspects of the bladder neck suspension procedure.

DESCRIPTION OF NON CLINICAL TESTS

The mean failure load of the *UroTac* Bone Anchor, when pulled from pubic bone, has been tested in a manner consistent with the Guidance Document for Testing Bone Anchor Devices (Draft November 1, 1993).

CONCLUSIONS FROM TESTS

The mean fixation strength of the device was demonstrated to be substantially equivalent to that of the Mitek predicate device. The tests did not yield any data suggesting safety or effectiveness issues which are other than those presented by the Mitek predicate device or the Microvasive bladder neck suspension procedure using the Vesica Bone Anchor.