2/16/99

510(k) Summary of Safety and Effectiveness
Influence, Inc.'s *MicroTac Bone Anchor System*
510(k) Number K990160

This 510(k) notification is submitted by Influence, Inc., 71 Stevenson Street, Suite 1120, San Francisco, California 94105. The contact person is Peter Bick, M.D., President and CEO.

This 510(k) notification describes a device intended for soft tissue fixation to the pubic bone by means of bone anchors threaded with sutures. It is indicated for cystourethropexy and vaginal sling procedures for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The *MicroTac* Bone Anchor System is substantially equivalent to Influence, Inc.'s *In-Tac* Bone Anchor System cleared under K964953 with respect to intended use, materials and performance of the bone anchors. The major differences between the two systems are that the inserter of the *MicroTac* Bone Anchor System is designed for single use and is manual, while the predicate device is designed for multiple use and uses springs to deliver energy to the bone anchors.

Information on risk analysis of the modifications and performance testing provided in the application demonstrates equivalence to the predicate device with respect to performance.

Based on the performance data gathered, the device modifications do not raise any new questions of safety or effectiveness.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 1999

Peter A. Bick, M.D.
President and CEO
Influence, Inc.
71 Stevenson Street, Suite 1120
San Francisco, California 94105

Re: K990160
Trade Name: MicroTac Bone Anchor System
Regulatory Class: II
Product Codes: MBI and HXJ
Dated: January 12, 1999
Received: January 19, 1999

Dear Dr. Bick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number (if known): K990160

Device Name: *MicroTac* Bone Anchor System, consisting of the *MicroTac* Bone Anchor and the *MicroTac* Bone Anchor Inserter

Indications for Use: The *MicroTac* Bone Anchor System is intended for soft tissue fixation to the pubic bone by means of bone anchors threaded with sutures. It is indicated for cystourethropexy and vaginal sling procedures for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number K990160

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use_____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990160