OCT - 9 1997

**510(k) Summary of Safety and Effectiveness**
**Influence, Inc.'s *Straight-In* Bone Screw Fixation System**
**510(k) Number** K972622

This 510(k) notification is submitted by Influence, Inc., 601 Montgomery Street, Suite 845, San Francisco, California 94111. The contact person is Mark D. Kramer, Consultant to Influence, Inc.

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 threaded with suture. The *Straight-In* Bone Screw Fixation System is indicated for use during open or laparoscopic surgical procedures where soft tissue fixation to the pubic bone is needed (e.g., bladder neck suspension and urethral sling procedures for female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency).

The *Straight-In* Bone Screw Fixation System is substantially equivalent to Influence, Inc.'s *In-Fast* Bone Screw System cleared under K970292 and the *Vesica* Suture Anchor System cleared under K932925. The mechanical properties and device materials of the *Straight-In* and *In-Fast* systems are identical. In both devices, fixation of soft tissue to bone is accomplished by a sharp tipped small diameter bone screw threaded with polypropylene suture. The In-Fast system is inserted pervaginally through soft tissue and into the pubic bone, without drilling holes or performing soft tissue dissection. The *Straight-In* Bone Screw Fixation System uses the identical bone screws and suture, but has a long, straight and narrow Inserter suitable for use in open and laparoscopic surgical procedures where soft tissue fixation to the pubic bone is needed. Like the *Vesica* system, the *Straight-In* uses an abdominal access procedure for soft tissue fixation to the pubic bone.

Performance testing provided and referenced in the application demonstrates equivalence to the predicate devices with respect to performance.

Based on the information provided, the *Straight-In* Bone Screw Fixation System is substantially equivalent to the *In-Fast* and *Vesica* devices 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

Mr. Mark D. Kramer
Consultant to Influence, Inc.
12037 Winesap Terrace
North Potomac, Maryland 20878-2331

OCT - 9 1997

Re: K972622
Trade Name: *Straight-In* Bone Screw Fixation System
Regulatory Class: II
Product Code: MBI
Dated: July 14, 1997
Received: July 14, 1997

Dear Mr. Kramer:

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

**510(k) Number (if known):** K972622

**Device Name:** *Straight-In* Bone Screw System, consisting of the *Straight-In* Bone Screw Inserter and *Straight-In* Bone Screws

**Indications for Use:** The *Straight-In* Bone Screw Fixation System is intended for soft tissue fixation to the pubic bone by means of bone screws threaded with suture. It is indicated for use during open or laparoscopic surgical procedures where soft tissue fixation to the pubic bone is needed (e.g., bladder neck suspension and urethral sling procedures for female stress 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 K972622

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)