AUG 3 1 1998

510(k) Summary of Safety and Effectiveness
Influence, Inc.'s *Short Shaft Straight-In* Bone Screw Fixation System
510(k) Number K982155

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 bones in the pelvic region (e.g., pubic, sacral, etc.) by means of bone screws threaded with suture. The *Short Shaft Straight-In* Bone Screw Fixation System is indicated for use during open surgical procedures where soft tissue fixation to bones in the pelvic region 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, sling procedure for male stress urinary incontinence resulting from prostatectomy).

The *Short Shaft Straight-In* Bone Screw Fixation System is substantially equivalent to Influence, Inc.'s *Straight-In* Bone Screw System cleared under K972622. The design and materials of the *Short Shaft Straight-In* and *Straight-In* systems are identical. The only difference is that the Inserter of the *Short Straight-In* device is shorter to serve the needs of users who prefer the maneuverability of a shorter device in open surgical procedures.

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

Based on the information provided, the *Short Shaft Straight-In* Bone Screw Fixation System is substantially equivalent to the *Straight-In* device 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

AUG 31 1998

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

Re: K982155
Trade Name: Short Shaft Straight-In Bone Screw Fixation System
Regulatory Class: II
Product Codes: MBI and HWC
Dated: June 18, 1998
Received: June 18, 1998

Dear Dr. Bick:

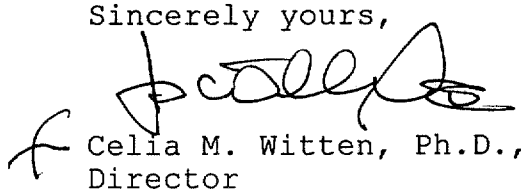
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

510(k) Number (if known): K982155

Device Name: *Short Shaft Straight-In* Bone Screw System

Indications for Use: The *Short Shaft Straight-In* Bone Screw Fixation System is intended for soft tissue fixation to bones in the pelvic region (e.g., pubic, sacral, etc.) by means of bone screws threaded with suture. It is indicated for use during open surgical procedures where soft tissue fixation to bones in the pelvic region 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, sling procedure for male stress urinary incontinence resulting from prostatectomy).

(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 K982155

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982155

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