FEB 1 1999

510(k) Summary of Safety and Effectiveness
Influence, Inc.'s Orthopedic *Straight-In* Bone Screw Fixation System
510(k) Number K990095

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 by means of bone screws threaded with sutures. The Orthopedic *Straight-In* Bone Screw Fixation System is indicated for use during surgical procedures where soft tissue fixation to bones is needed, such as:

1. Repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromiociavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction.
2. Repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation.
3. Repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament.
4. Repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis.
5. Repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments.

The *Straight-In* – Orthopedic Bone Screw Fixation System is substantially equivalent to Influence, Inc.'s Short Shaft *Straight-In* Bone Screw System cleared under K982155. The design and materials of the Orthopedic *Straight-In* and Short shaft *Straight-In* systems are identical. The differences are that the Inserter of the Orthopedic *Straight-In* is designed for use in 10 procedures, while the predicate device is designed for single use. The Orthopedic device is substantially equivalent to the Anchorlok™ Soft tissue anchor system cleared under K971282 with respect to intended use and performance of the bone screws.

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 *Straight-In* Orthopedic Bone Screw Fixation System is substantially equivalent to the Short Shaft *Straight-In* and to the Anchorlok™ devices with respect to intended use, technological characteristics, and performance.

INDICATIONS FOR USE

510(k) Number (if known): K990095

Device Name: *Straight-In* – Orthopedic Bone Screw System

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

510(k) Number K990095

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1999

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

Re: K990095
Trade Name: *Straight-In*-Orthopedic Bone Screw Fixation System
Regulatory Class: II
Product Code: MBI and HWC
Dated: December 31, 1998
Received: January 12, 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

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(Division Sign-off) MRPO
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