

**510(k) Summary of Safety and Effectiveness
Influence, Inc.'s *Influence Clip System***

510(k) Number _____ K981631

Submitter's Name:

Peter A. Bick, M.D., President and CEO
Influence, Inc.
71 Stevenson Street, Suite 1120
San Francisco, California 94105
Telephone: 415-546-7700 / Fax: 415-546-7744

Device:

Trade name: *Influence Clip System*
Classification Name: Implantable Clip
Product Code: 79FZP

Predicate Devices:

United States Surgical Corporation's Auto Suture Suture Closure (K954853),
Innovasive Devices, Inc.'s Y-Knot Suture Clip (K973313), and Howmedica,
Inc.'s Dall-Miles Cable Grip System (K900926).

Indication for Use:

The *Influence Clip System* is indicated for permanent securing of two strands of surgical suture for soft tissue approximation in open or laparoscopic surgical procedures.

Device Description:

The *Influence Clip System* has two components, a suture clip and an applier. To fixate sutures, the stainless steel clip is inserted into the applier. Two strands of suture are threaded through the clip and the applier inserted into the trocar (if a laparoscopic procedure is performed). The applier's handle is then tightly squeezed which causes a rod within the applier's shaft to crimp the clip around the sutures. The sutures' ends are cut close to the clip (alternative version of applier with suture cutter may be used). The system is provided sterile and the applier is disposable, for single patient use.

Technological Characteristics and Performance:

All materials used in the *Influence Clip System* are either commonly used in medical applications or have been proven to be biocompatible through

biocompatibility testing. Bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to a 510(k)-cleared device.



JUL 28 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981631
Trade Name: Influence Clip System
Regulatory Class: II
Product Code: FZP
Dated: May 4, 1998
Received: May 7, 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.

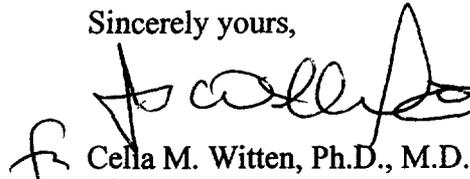
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4595. 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,

A handwritten signature in black ink, appearing to read "C. M. Witten". The signature is written in a cursive style with a large initial "C" and "M".

Cella 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): K981631

Device Name: *Influence Clip System, consisting of the Influence Clip System Applier and Influence Clip System Suture Clip*

Indications for Use: The *Influence Clip System* is intended for permanent securing of two strands of surgical suture for soft tissue approximation in open or laparoscopic surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)

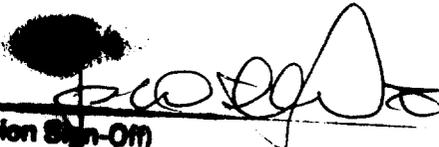
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____



(Division Sign-Off)
Division of General Resto
510(k) Number K981631