SEP 19 1997

K972651

510(k) Summary

Influence, Inc.'s *IN-SLING*™

** For Release Upon Request Only **

Submitter's Name:

Influence, Inc.
601 Montgomery Street, Suite 845
San Francisco, California 94111

Contact Person:

Peter A. Bick, M.D.
President and CEO
Influence, Inc.
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San Francisco, California 94111
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Date Prepared:

July 11, 1997

Trade Name:

IN-SLING™

Classification Name:

Mesh, Surgical, Polimeric

Classification:

The FDA has classified surgical mesh as a class II device (product code OTN, PAG) and it is reviewed by the Plastic and Reconstructive Surgery Devices Branch.

Predicate Devices:

- Surgical Fabrics' *ProteGen*™ (K963226)
- Vascutek's *Gelseal*™ (K963611)

Performance Standards:

No performance standards applicable to surgical mesh have been established by the FDA.

Indication for Use:

The *IN-SLING*™ is intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence

Device Description:

The *IN-SLING*™ is a gelatin-sealed, knitted polyester patch fabric intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence.

Technological Characteristics and Substantial Equivalence:

The *IN-SLING*™ is identical to the *Vascutek Gelseal*™ in terms of materials, manufacturing, processing, packaging and sterilization. The only difference between the *IN-SLING* and the *Vascutek Gelseal*™ is in the size and shape of the fabric.

The *IN-SLING* is substantially equivalence to Surgical Fabrics' *ProteGen*™ in terms of intended use and labeling. Like the *ProteGen*™ is used with the *Vesica System* as a sling in sling procedures, the *IN-SLING*™ is used as a sling with Influence's transvaginal surgical systems (*In-Fast* and *In-Tac*) in sling procedures for the treatment of urinary incontinence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

Peter A. Bick, M.D.
President and CEO
Influence, Inc.
601 Montgomery Street, Suite 845
SAN FRANCISCO CA 94111

Re: K972651
Trade/Device Name: *IN-SLING*™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN, PAG
Dated: July 14, 1997
Received: July 14, 1997

Dear Dr. Bick:

This letter corrects our substantially equivalent letter of September 19, 1997.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

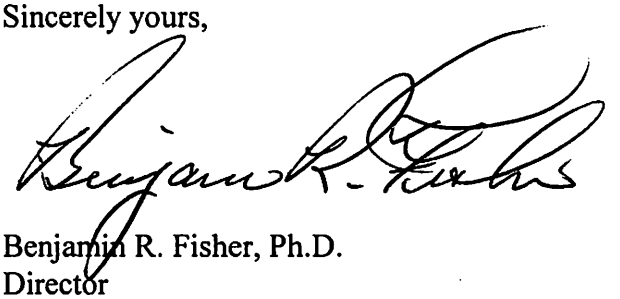
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K972651

Device Name: IN-SLING

Indications For Use:

IN-SLING is intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence.

(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 Restorative Devices
510(k) Number K972651

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)