

K980482

510(k) Summary
Influence, Inc.'s TriAngle Sling
510(k) Number K980482

MAR 27 1998

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

Trade Name:

TriAngle Sling

Classification Name:

Mesh, Surgical, Polymeric (OTN)

Predicate Device:

Influence In-Sling (K972651)

Indication for Use:

The TriAngle Sling is intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence.

Device Description:

The TriAngle Sling is a knitted patch fabric intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence.

Technological Characteristics and Performance:

The TriAngle Sling is very similar to the Influence In-Sling. Performance testing and information in the application demonstrated that TriAngle sling is biocompatible and provides equivalent performance to the In-Sling.



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

Mr. Mark D. Kramer
Consultant to Influence, Incorporated
11812 Quince Mill Drive
NORTH POTOMAC MD 20878

SEP 28 2012

Re: K980482
Trade/Device Name: TriAngle Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: February 9, 1998
Received: February 9, 1998

Dear Mr. Kramer:

This letter corrects our substantially equivalent letter of March 27, 1998.

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.

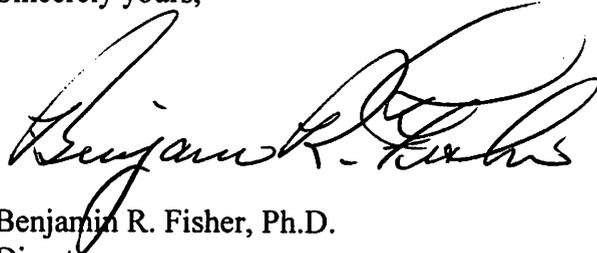
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name being the most prominent.

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

INDICATIONS FOR USE

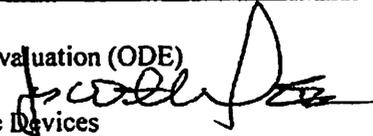
510(k) Number (if known): K980482

Device Name: TriAngle Sling

Indications for Use: The TriAngle Sling is indicated 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 and Restorative Devices



510(k) Number K980482

Prescription Use
(Per 21 CFR 801.109)

OR

Over the Counter Use
