K983325

NOV 24 1998

510(k) Summary
Influence, Inc.'s In-Probe II Urodynamics System
510(k) Number _____

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:

In-Probe II Urodynamics System

Classification Name:

Urodynamics Measurement System (78 FEN)

Predicate Devices:

In-Probe II Urodynamics System is substantially equivalent to Influence, Inc.'s In-Probe Urodynamics System, which is 510(k) exempted and was listed under A0995505. The In-Probe II Urodynamics System has an angle sensor that is substantially equivalent technologically to Andronic Devices, Ltd.'s Insight electronic alignment indicator cleared under K940812, and to the preamendments Q-tip test in terms of intended use.

Indication for Use:

The In-Probe II Urodynamic System is indicated as an aid in the diagnosis of voiding dysfunction in males and females. In females, the In-Probe II Urodynamic System is also indicated for measuring urethral angle during straining.

Device Description:

The In-Probe II Urodynamic System is a compact and portable urodynamic system capable of performing cystometrography (CMG) for both men and women. In addition, for women, the device can provide objective measurement of the changes in urethral angle that occur during patient straining.

Technological Characteristics and Performance:

The In-Probe II is very similar to the In-Probe Urodynamics system, but has one additional capability – urethral angle measurement. Performance testing and information in the application demonstrated that the In-Probe II system is biocompatible and provides equivalent performance to the original In-Probe Urodynamics System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983325
Influence, Inc.'s In-Probe Urodynamic System
Dated: September 15, 1998
Received: September 22, 1998
Regulatory Class: II
21 CFR 876.1620/Procode: 78 FEN

Dear Dr. Bick:

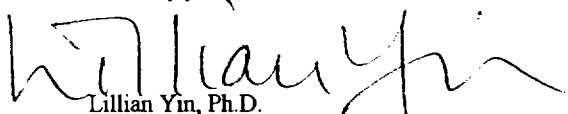
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: In-Probe II Urodynamic System, consisting of the In-Probe controller, urethral rectal and angle probes, and other accessories.

Indications for Use: The In-Probe II Urodynamic System is indicated as an aid in the diagnosis of voiding dysfunction in males and females. In females, the In-Probe II Urodynamic System is also indicated for measuring urethral angle during straining.

(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 √ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983325