

K9 72023

Aug 25

510(k) Summary

Influence, Inc.'s Sleep-In™ Bone Screw System

Company Name:

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

Submitter's Name and Contact Person:

Peter Bick, M.D., President and CEO
Influence, Inc.
601 Montgomery Street, Suite 845
San Francisco, California 94111
Telephone: 415-421-5600
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Date Prepared:

May 29, 1997

Trade/Proprietary Name:

Sleep-In™ Bone Screw System

Classification Name:

The Sleep-In™ Bone Screw System has not yet been classified.

Predicate Devices:

Sleep-In™ Bone Screw and Sleep-In™ Bone Inserter:

- In-Fast™ Bone Screw System (K970292)
- Mitek GII Anchor (K920213)
- PM Positioner™ (K953293 & K955503)
- Snor-X Mouthguard (K954324)

Sleep-In™ Suture Passer:

- Protecta-Pass™ Suture Passer (K932925)

Performance Standards:

No performance standards applicable to the bone screw systems have been established by the FDA. However, the titanium alloy 6AL-4V Eli alloy used to manufacture the Sleep-In™ Bone Screw meets the chemical and mechanical requirements in voluntary standards established by ASTM (F136-84).

Intended Use:

The Sleep-In™ Bone Screw System is intended for anterior advancement and suspension of the tongue base by means of a bone screw threaded with suture. It is indicated for the treatment of obstructive sleep apnea (“OSA”) and/or snoring.

System Description:

The Sleep-In™ Bone Screw System consists of three main components: a bone screw attached to surgical suture material, a bone screw inserter, and a suture passer. The Sleep-In™ Bone Screw is a sharp tipped, small diameter titanium screw with polypropylene monofilament no. 1 suture crimped into its base.

The Sleep-In™ Bone Screw Inserter is a disposable, battery operated, single use device. The Sleep-In™ Suture Passer is designed to assist in passing the suture through the floor of the tongue during the Sleep-In™ procedure.

Technological Characteristics and Substantial Equivalence:

The performance characteristics of the Sleep-In™ Bone Screw System has been tested and approved through a series of *in vitro* and *in vivo* studies.

Furthermore, initial clinical experience with the Sleep-In™ Bone Screw System has demonstrated its potential for treating patients suffering from OSA and/or snoring.

The Sleep-In™ Bone Screw System, like its predicate devices the In-Fast™ Bone Screw System and the Mitek GII Anchor, is based on suspending soft tissue to fixed bone by means of sutures attached to bone screw.

In respect to the procedure, the Sleep-In™ System procedure is based upon well accepted and commonly used procedures like *Hyoid Bone Suspension*, *Chin Osteotomy* and *Mandibular Advancement* for the treatment of OSA and/or snoring.

The Sleep-In™ Bone Screw System is substantially equivalent to PM Positioner™ and the Snor-X Mouthguard with respect to the intended use for the treatment of OSA and/or snoring by means of repositioning of the tongue.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2009

David Guzek
Sr. Regulatory Specialist
Medtronic ENT
Medtronic USA, Inc.
6743 Southpoint Dr., N.
Jacksonville, FL 32216-0980

Re: K972023
K981677

Dear Mr. Guzek:

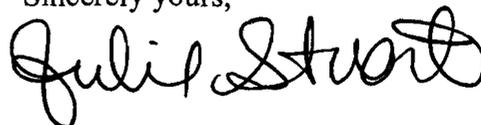
We have reviewed your letters, received January 8, 2009, stating that the rights to the above referenced premarket notification (510(k)) have been transferred. Transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitter in our database. Please note, as per 21 CFR 807.85(b), a firm may not both manufacture and distribute a device under their own name without having their own 510(k).

We suggest that information showing the transfer of the 510(k) and its current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276-0100 if you have any questions on what information we expect to be maintained in your files.

"Please note, under 21 CFR 807.81(a)(2) a firm may not both retain and transfer 510(k) marketing rights to another person, e.g., a contract manufacturer, because each person who manufactures and distributes a device must have their own 510(k), if the device is not exempt from the premarket notification requirement. Likewise, distributors need 510(k) clearances before marketing devices when they alter them by doing more than putting their name on the device, because such actions would disqualify them from the 510(k) distributor exemption under 21 CFR 807.85(b)."

If you have any other questions regarding this letter, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

A handwritten signature in black ink that reads "Julie Stuart". The signature is written in a cursive, flowing style.

Julie "Brandi" Stuart
Consumer Safety Officer
Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: Influence, Inc.
601 Montgomery Street, Suite 845
San Francisco, CA 94111

Influence, Inc.
c/o Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Sleep-In™ Bone Screw System

Indications for Use: The Sleep-In™ Bone Screw System is intended for anterior advancement of the tongue base by means of a bone screw threaded with suture. It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring.

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

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

510(k) Number KA72023

Sharon Sumner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number KA72023

Prescription Use
(Per 21 CFR 801.109)

OR

Over the Counter
Use _____