K981677

AUG 27 1999

510(k) Summary

Influence, Inc.'s Repose™ Bone Screw System

Company Name:

Influence, Inc.
71 Stevenson Street, Suite 1120
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Submitter's Name and Contact Person:

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or

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Date Prepared:

May 11, 1998

Trade/Proprietary Name:

Repose™ Bone Screw System

Classification Name:

The Repose Bone Screw System has not yet been classified.

Predicate Devices:

Repose™ Bone Screw System:

- Sleep-In™ Bone Screw System (K972023)
- In-Fast™ Bone Screw System (K970292)
- Mitek GII Anchor (K920213)

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 Repose Bone Screw meets the chemical and mechanical requirements in voluntary standards established by ASTM (F136-84).

Intended Use:

The Repose™ Bone Screw System is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is also suitable for the performance of a hyoid procedure. It is indicated for the treatment of obstructive sleep apnea ("OSA") and/or snoring.

System Description:

The Repose™ 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 Repose™ Bone Screw is a sharp tipped, small diameter titanium screw with polypropylene monofilament no. 1 suture crimped into its base.

The Repose™ Bone Screw Inserter is a disposable, battery operated, single use device. The Repose™ Suture Passer is designed to assist in passing the suture through the floor of the tongue in a tongue base advancement procedure or through the neck during a hyoid suspension procedure.

Technological Characteristics and Substantial Equivalence:

The performance characteristics of the Repose™ Bone Screw System has been tested and approved through a series of *in vitro* and *in vivo* studies, previously submitted under 510(k): K972023 for Influence Inc's Sleep-In™ Bone Screw System.

The Repose™ Bone Screw System, like its predicate devices the Sleep-In™ Bone Screw System, 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 Repose™ System procedure is based upon well accepted and commonly used procedures like *Hyoid Bone Suspension, Chin Osteotomy* and *Genioglossal Advancement* for the treatment of OSA and/or snoring.

The Repose™ Bone Screw System is substantially equivalent to the Sleep-In™ Bone Screw System with respect to the intended use for the treatment of OSA and/or snoring by means of repositioning of the tongue and to the commonly

accepted practice of *Hyoid Bone Suspension* by means of tongue base advancement via the hyoid bone which is attached to the tongue base musculature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2009

David Guzek
Sr. Regulatory Specialist
Medtronic ENT
Medtronic USA, Inc.
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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,

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.
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INDICATIONS FOR USE

510(k) Number (if known): K981677

Device Name: Repose™ Bone Screw System

Indications for Use: The Repose™ Bone Screw System is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is also suitable for the performance of a hyoid suspension procedure as an adjunct to tongue base suspension. 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)

(Division Sign-Off)
Division of Dental, Infection Control
and General Hospital Devices
510(k) Number K981677

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Prescription Use ✓ OR Over the Counter