K063380

510(k) ECHOSTIM FACET TIP
HAVEL'S INC.

APR 25 2007

A. DEVICE NAME

Proprietary Name(s): EchoStim Facet Tip

Common Name(s): Kit Conduction Anesthetic

B. Establishment Registration Number: 9611481

C. Address of Manufacturing Site and Distributor:

Manufacturer:

HAKKO MEDICAL CO., LTD
3055, Togura, Oaza Togura-machi
Hanishina-gun, Nagano-ken 389-08, Japan

Distributor:

Havel's Inc.
3726 Lonsdale Street
Cincinnati, OH 45227

D. Classification:

Device Classification Name: Kit, Conduction Anesthetic

21CFR 868.5140 Class II

Product Code: CAZ BSP

E. Statement of substantial equivalence:

Predicate Devices:

1. UniPlex Cannula, K000722, Pajunk Gmbh.
2. Plexalong Set, K013041, Pajunk Gmbh.

The EchoStim Facet Tip Needle is substantially equivalent to the Pajunk needle predicated devices in that it is similar with respect to materials, technological characteristics and intended use.

A comparison chart of the two devices is attached.

F. Indication for use:

Havel's electrically insulated anesthesia conduction needles are used to puncture the tissue in order to gain entry and locally inject anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician to pinpoint the area of application.

G. Description of device(s):

Drawings and a bill of materials for the EchoStim device are attached.

H. Sterilization

Sterilization is by ETO and is validated to 10^{-6}.

I. Performance standards/special controls:

Performance standards under Section 514 of the Act have not been developed for these devices.

J. Proposed labeling:
Draft labeling is attached.

Each Product Label will have the following information:

Complete product description

Manufactured by: Hakko Medical Co., Ltd.

Distributed by: Havel's Incorporated
3726 Lonsdale Street
Cincinnati, Oh 45227
(513) 271-2117
Made in Japan

STERILE SINGLE USE ONLY

CAUTION: Do not use if package has been opened or damaged. Store in a cool, dry place. Federal law restricts this device to sale by or on the order of a physician.

Sterile unless opened or damaged

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Patrick Carrothers
Vice President Marketing
Havel's, Incorporated
3726 Lonsdale Street
Cincinnati, Ohio 45227

APR 25 2007

Re: K063380
Trade/Device Name: EchoStim Facet Tip
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: April 4, 2007
Received: April 10, 2007

Dear Mr. Carrothers:

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 application (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.

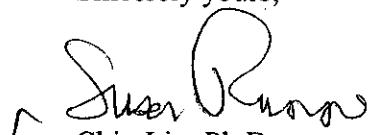
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k)NUMBER K063380

DEVICE NAME: EchoStim Facet Tip

INDICATION FOR USE:

Havel's electrically insulated anesthesia conduction needles are used to puncture the tissue in order to gain entry and locally inject anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician to pinpoint the area of application.

Prescription Use _X_ (Per 21 CFE 801.109) OR Over-The-Counter-Use ____ (Options Format 1-2-96)

(please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]

[illegible] of Anesthesiology, General Hospital,
[illegible]ion Control, Dental Devices

[illegible]k) Number K063380