K070052

MAR 2 8 2007

VILEX Inc.

Manufacturer of Vilex™ bone implants, Power equipment & surgical instruments
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SUMMARY

Met-Head™, Resurfacing Hemi-Arthroplasty Implant

The implant is a fixation metal device, machined from implant quality cobalt-chrome alloy. The implant is cannulated to allow proper positioning. The stem is threaded and functions as a self-reaming and self-tapping screw for easy insertion. The shaft design is a duplicate of Vilex Cannulated Hemi Implant, K023684. The head is spherical and mirror-polished. The outside appearance resembles the STD Great Toe Resurfacing Hemi-Arthroplasty Implant, K031859. **Use** Only **with Approved Bone Cement**

Auxiliary instruments for implanting, aligning, countersinking come with "The Met-head."

Date of submission	December 26, 2006, rev4: March 13, 2007
Type of submission	510(k); K070052
Reason for submissi	New Device
Product Code	KWD
Device Class	II
Classification Panel	Orthopedics
Predicate Devices: K023684 K031859	 Vilex STD Manufacturing
Common/Generic	**Phalangeal (Hemi Toe) Prosthesis**
Device Trade Name	Met-Head™
Establishment Reg.	2529556
Owner Operator No.	9004058
Establishment Operations	Manufacturer
Indication for Use	Hallux Limitus or Rigidus Resurfacing of Arthritic /Metatarsal joint To fixate, use cement or press fit without cement
Submitter	Sylvia Southard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vilex, Inc
% Ms. Sylvia Southard
President
111 Moffitt Street
McMinnville, Tennessee 37110

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Re: K070052
Trade/Device Name: Met-Head™
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: December 26, 2006
Received: January 10, 2007

Dear Ms. Southard:

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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510 (K) NUMBER K070052

DEVICE NAME: **Toe Joint, Phalangeal (Hemi Toe) Prosthesis, Trade Name "Met-Head™"**

INDICATIONS FOR USE:

The Vilex "The Met-head", as designed, has the following Indications for Use:

Hallux Limitus or Rigidus
Halux Valgus
Metatarsal/Phalangeal (MTP) Joint
To fixate, use cement or press fit without cement

Prescription Use __X__
(Per 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070052

Concurrence of CDRH, Office of Device Evaluation (ODE)