



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Vilex, Incorporated
% Abraham Lavi, Ph.D.
Consultant
8374 Market Street, #167
Lakewood Ranch, Florida 34202

October 29, 2015

Re: K151456
Trade/Device Name: Small Bone Nail Implant
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 28, 2015
Received: September 29, 2015

Dear Dr. Lavi:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



INDICATIONS FOR USE

ADVANCE WITH US >>>

510(k) Number: K151456

DEVICE NAME: Small Bone Nail Implant (SBNI)

INDICATIONS FOR USE

The Tapered Small Bone Nail Implant (SBNI) is indicated for use in fractures and osteotomies of the fibula, radius, and ulna.

Prescription Use X
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (DOE)



ADVANCE WITH US >>>

510(k) Summary
Small Bone Nail Implant System
K151456

Sponsor:	Vilex, Inc. 111 Moffitt Street McMinnville, TN 37110 Phone: (931) 474-7550 Fax: (931) 474-7551
Contact:	Abraham Lavi
Date Prepared:	September 22, 2015
Trade Name:	Small Bone Nail Implant System
Common Name:	Intramedullary Fixation Rod
Classification Name:	21 CFR Section 888.3020 Rod, Fixation, Intramedullary And Accessories
Device Class:	Class II
Product Code:	HSB/ Orthopedics
Predicate Devices:	Acumed Small Bone Locking Rod System (K031438 and K071944) Biomet Titanium Intramedullary Rods-VariouS Styles (K982953) and Kirschner (now Biomet, Inc.) Intramedullary Nail System (K854338) Arthrex Opening Wedge Osteotomy System (K973812) Arthrex Low Profile Plate and Screw System (K052614)
Description of Device:	The Vilex Small Bone Nail Implant System includes Tapered Nails (straight or bowed) and Locking Screws.
Indications for Use:	The Tapered Small Bone Nail Implant (SBNI) is indicated for use in fractures and osteotomies of the fibula, radius, and ulna.

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510(k) Summary
Small Bone Nail Implant System
K151456

Technological Characteristics:	The technological characteristics for the Small Bone Nail Implant System are similar to the characteristics of the predicate devices. The sizes included in the Small Bone Nail Implant System are similar to the range of offerings of the predicate devices and the designs of the Small Bone Nail Implant System are similar to the predicate devices. The materials used to manufacture the Small Bone Nail Implant System are implant grade materials appropriate for intramedullary nails.
Substantial Equivalence:	The design features of the Small Bone Nail Implant are substantially equivalent to the design features of other predicate devices previously cleared for market. The claim of substantial equivalence of the Small Bone Nail Implant System to the predicate devices is based on the comparison of the intended use, product technical characteristics and performance characteristics. Comparisons confirmed that the Small Bone Nail Implant is as safe, as effective and should perform as well as or better than the predicate devices. While the Small Bone Nail Implant System is not identical to the predicate devices, comparisons of the subject and predicate devices confirmed that any differences between the subject device and predicates do not render the device NSE as there is not a new intended use; and any differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate devices. Therefore, it is concluded that the Small Bone Nail Implant System is substantially equivalent to the predicate devices as outlined previously.
Conclusions:	While the devices in the Small Bone Nail Implant System are not identical to the predicate devices, any differences that may exist do not significantly affect device safety and effectiveness. In addition, the differences do not add new or increased risks and complications. Therefore, it is concluded that the Small Bone Nail Implant System is substantially equivalent to the predicate devices as outlined previously and should not render the subject device NSE.