



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

Vivorté, Incorporated
% Stephen J. Peoples, VMD, MS
Peoples & Associates
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

January 14, 2015

Re: K143549

Trade/Device Name: Vivorté Trabexus™

Regulation Number: 21 CFR 888.3045

Regulation Name: Resorbable calcium salt bone void filler device

Regulatory Class: Class II

Product Code: MQV

Dated: December 12, 2014

Received: December 15, 2014

Dear Dr. Peoples:

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 Statement

510(k) Number K143549

Device Name: Vivorté Trabexus™

Indications for Use:

Vivorté Trabexus™ is a moldable, self-setting, gradually resorbable, calcium phosphate bone void filler. Vivorté Trabexus™ is indicated for use to fill bony voids or defects of the skeletal system (i.e., extremities, pelvis) that may be surgically created or osseous defects created from traumatic injury to the bone and only for bony voids or defects that are not intrinsic to the stability of the bony structure. Vivorté Trabexus™ may be manually applied to the bony defect or applied to the defect through a cannula. Vivorté Trabexus™ is resorbed and remodeled by the body as new bone formation occurs during the healing process.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

This 510(k) Summary is provided per the requirements of 21 CFR 807.92.

Submitter Information:

Name: Vivorté, Inc.
Address: 1044 E. Chestnut Street
Louisville, KY 40204
Telephone: (502) 693-2432
Fax: (502) 714-7235

Contact Person: Robert Burden
Date Prepared: December 12, 2014

Device Information:

Trade Name: Vivorté Trabexus™
Common Name: Calcium bone void filler
Classification: Class II
Regulation Number and Description: 21 CFR 888.3045 - Resorbable calcium salt bone void filler device
Product Code: MQV

Predicate Device:

The predicate device is Vivorté BVF™ Lite™ that was cleared via 510(k) K131133 on August 12, 2013.

Device Description:

Vivorté Trabexus™ is a moldable, self-setting, gradually resorbable, biocompatible, calcium phosphate bone void filler. The device is provided in kit sizes of 3 cc, 5 cc, and 10 cc, corresponding to the amount of bone void filler produced when the components of the kit are mixed together.

Indications for Use:

Vivorté Trabexus™ is a moldable, self-setting, gradually resorbable, calcium phosphate bone void filler. Vivorté Trabexus™ is indicated for use to fill bony voids or defects of the skeletal system (i.e., extremities, pelvis) that may be surgically created or osseous defects created from traumatic injury to the bone and only for bony voids or defects that are not intrinsic to the stability of the bony structure. Vivorté Trabexus™ may be manually applied to the defect or

applied to the defect through a cannula. Vivorté Trabexus™ is gradually resorbed and remodeled by the body as new bone formation occurs during the healing process.

Comparison to Predicate Device:

The subject Vivorté Trabexus™ is essentially the same as the predicate device. The only difference between the predicate and the subject device is that the subject device includes an additional accessory, a delivery cannula to deliver the calcium phosphate bone filler to the bone defect site as specified in the indications for use cleared in K131133. The primary packaging was modified to accommodate the additional accessory and the Instructions for Use were modified to instruct the physician how to use the additional accessory delivery cannula. The changes made to the Instructions for Use do not affect the intended use.

Non-Clinical Testing:

Performance testing according to the design verification test methods indicated by the risk analysis was conducted. A summary of the test results is included below.

Comparative Testing

Test Method	Subject Device Test Results
Extrudability	Not applicable
Biocompatibility	Pass
Bubble leak test	Pass
Heat seal strength of primary packaging	Pass

Substantial Equivalence:

In establishing substantial equivalence to the predicate device, Vivorté evaluated the intended use and indications for use, materials, basic design, fundamental scientific technology, labeling, packaging materials and configuration, shelf life, and sterilization processes. The performance testing demonstrates that the subject device meets the acceptance criteria per the design verification test methods identified by the risk analysis. Based on the information presented, the proposed delivery cannula accessory does not impact the device safety and effectiveness and Vivorté Trabexus is substantially equivalent to the predicate Vivorté BVF Lite cleared via K131133 on August 12, 2013.