



Food and Drug Administration
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Avitus Orthopaedics Incorporated
Mr. Maxim Budyansky
Copresident, Cofounder
400 Farmington Avenue, Suite R1717
Farmington, Connecticut 06032

October 23, 2015

Re: K152474

Trade/Device Name: Avitus™ Bone Harvester
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: August 28, 2015
Received: August 31, 2015

Dear Mr. Budyansky:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

For Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K152474

Device Name

Avitus(TM) Bone Harvester

Indications for Use (Describe)

The Avitus(TM) Bone Harvester is intended to harvest cancellous bone and marrow

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5

510(k) Summary

5.1 Submission Correspondent

Mr. Maxim Budyansky
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5.2 Submission Owners

Mr. Maxim Budyansky and Mr. Neil Shah
Co presidents, Co founders
Aventus Orthopaedics Inc.
400 Farmington CT RM R1717
Farmington CT 06032

5.3 Date Summary Prepared

August 28, 2015

5.4 Device Trade Name

Aventus™ Bone Harvester

5.5 Device Common Name

Bone harvester

5.6 Device Classification Name

Class II, Instrument, Biopsy, KNW at 21 CFR 876.1075.

*SECTION 5. 510(K) SUMMARY***5.7 Legally Marketed Device To Which The Device Is Substantially Equivalent**

The Avitus™ Bone Harvester is substantially equivalent to the MarrowMiner cleared under K071732.

5.8 Description Of The Device

The proposed device is a manual surgical instrument that cuts cancellous bone by manual actuation of the cutting tip. The cap contains a barbed nozzle that connects to standard sized suction tubing (tube with an ID of 6–10 mm) to connect to a vacuum source, wherein the vacuum source has a static maximum pressure between 150 mmHg and 750 mmHg. The proposed device can be connected to a waste canister that leads to standard operating room wall suction or to an external pump. With the device connected to a vacuum source, when actuated in bone the cutting tip carves, scrapes and cuts cancellous bone and collects the bone graft inside the handle. The suction pulls the bone and bone marrow from the cutting tip and into the bone reservoir inside the handle. The cap contains a filter that prevents material from escaping the handle into the suction system by utilizing a physical sieve to keep bone particulate in the handle. After harvesting, the bone graft can be retrieved from the handle.

5.9 Intended Use

The Avitus™ Bone Harvester is intended to harvest cancellous bone and bone marrow.

5.10 Technological Characteristics

The proposed device has the same technological characteristics as the predicate device(s). Specifically, both the proposed and predicate devices use a cutting edge and suction to harvest bone and/or bone marrow.

While there is a difference in the indication for use between proposed and predicated device, there is no impact on substantial equivalence. Specifically, the proposed Avitus™ Bone Harvester is intended to harvest both cancellous bone and bone marrow. The predicate MarrowMiner K071732 device is only cleared for collection of bone marrow. Both devices allow for the collection of these materials utilizing a cutting and suction action with no further direction given to the user regarding the use of the collected material. Therefore, there is no negative impact on safety and effectiveness regarding the indication for use.

5.11 Non-Clinical Testing

Tests were performed to demonstrate substantial equivalence in the following areas:

- Clinical Load Evaluation
- Worst Case Failure Of Cutting Tip Breakage

These tests concluded that the proposed device will perform in a manner that exceeds anticipated clinical loads and are therefore, substantially equivalent to the predicate MarrowMiner K071732 device.

*SECTION 5. 510(K) SUMMARY***5.12 Biocompatibility**

Materials were tested for cytotoxicity, sensitization, intracutaneous reactivity, and systemic toxicity. The materials were confirmed to be biocompatible.

5.13 Clinical Testing

No clinical testing was performed in association with this submission.

5.14 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.