March 31, 2021

Avitus Orthopaedics, Inc.
% William G. McLain
President and Principal Consultant
Keystone Regulatory Services, LLC
342 E. Main Street
Leola, Pennsylvania 17540

Re: K210631
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: March 1, 2021
Received: March 3, 2021

Dear William G. McLain:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210631

Device Name

Avitus® Bone Harvester

Indications for Use *(Describe)*

The Avitus® Bone Harvester is intended to harvest cancellous bone and marrow; to debride and capture infected, necrotic or diseased cancellous bone (e.g. osteomyelitis, cancellous bone tumors).

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.

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Section 5

510(k) Summary

5.1 Submission Owner and Correspondent

Submission Owner

Avitus Orthopaedics, Inc.
Mr. Maxim Budyansky and Mr. Neil Shah
Co-Presidents, Co-Founders
6 Armstrong Rd. 2nd Floor
Shelton, CT 06484

Submission Correspondent

Additionally, the following individual is identified as a submission correspondent.

Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, PA 17540
Contact: William McLain
Phone: 717-656-9656
E-Mail: bill.mclain@keystoneregulatory.com

5.2 Date Summary Prepared

March 1, 2021

5.3 Device Trade Name

Avitus® Bone Harvester

5.4 Device Common Name

Bone Harvester

5.5 Device Classification Name

Instrument, Biopsy Classified as Class 2, product code KNW at 21 CFR 876.1075

5.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

The Avitus® Bone Harvester is substantially equivalent to the Avitus® Bone Harvester cleared under K170539.

5.7 Description of the Device

The proposed device is a minimally invasive manual non-powered cancellous bone and marrow graft harvester that can also be used for the removal of infected, necrotic, and diseased cancellous bone. The proposed changes described in this submission add to the types of materials to be collected to include infected, necrotic, or diseased cancellous bone. The Avitus® Bone Harvester consists of a metal cutting tip and shaft with transparent plastic handle, filter, collection chamber, and a threaded plastic cap.

The principles of action for the proposed device with revised indications for use are identical to the predicate device. The Avitus® Bone Harvester is a manual surgical instrument that harvests cancellous bone and marrow, and debrides infected, necrotic, or diseased cancellous bone by manual actuation of the cutting tip. The Cap contains a barbed nozzle that connects to standard sized suction tubing to connect to a vacuum source. With the device connected to a vacuum source, when actuated in bone the cutting tip carves, scrapes, cuts, and collects the material into the reservoir filter insert inside the Handle. The Cap has a filter feature that prevents material from escaping the handle into the suction system by utilizing a physical sieve to keep bone particulate in the handle.

5.8 Indications for Use

The Avitus® Bone Harvester is intended to harvest cancellous bone and marrow; to debride and capture infected, necrotic or diseased cancellous bone (e.g. osteomyelitis, cancellous bone tumors).

5.9 Technological Characteristics

The proposed modifications described in this submission have not resulted in any changes to technological characteristics. The overall design, materials of construction and sterilization methods remain the Same The only change is to modify the indications for use from:

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

to

> The Avitus® Bone Harvester is intended to harvest cancellous bone and marrow; to debride and capture infected, necrotic or diseased cancellous bone (e.g. osteomyelitis, cancellous bone tumors).

To account for differences in the indication for use, the Instructions for Use have been modified by:

- stating the revised indications for use,
- adjusting the contraindications, and
- providing procedural steps for removal of infected, necrotic, or diseased bone.

Table 5.1 provides additional detail regarding similarities and differences related to Technological Characteristics.

Table 5.1: Technological Characteristics Table

Feature	**Proposed Device - Avitus® Bone Harvester**	**Predicate Device - Avitus® Bone Harvester (K170539)**	**Comments on Similarities and Differences**
Classification Regulation, Product Code, and Review Panel	Class II, Product Code KNW, Classified at 21 CFR 876.1075, Gastroenterology-urology biopsy instrument review panel	Class II, Product Code KNW, Classified at 21 CFR 876.1075, Gastroenterology-urology biopsy instrument review panel	The classification regulation, product code and review panel for the proposed and predicate devices are identical. There are no differences.
Indications for Use	The Avitus® Bone Harvester is intended to harvest cancellous bone and marrow; to debride and capture infected, necrotic or diseased cancellous bone (e.g. osteomyelitis, cancellous bone tumors).	The Avitus® Bone Harvester is intended to harvest cancellous bone and marrow.	The indications for use are identical in relation to harvesting cancellous bone and marrow. They differ in that the proposed indication for use adds debridement and capture of infected, necrotic or diseased cancellous bone (e.g. osteomyelitis, cancellous bone tumors).
Diameters	5,6,8mm	5,6,8mm	The diameters are identical. There are no differences.
Collection Reservoir	Located inside handle proximal to the suction canister	Located inside handle proximal to the suction canister	The location of the collection reservoir is identical. There are no differences.
Cutting Tip	Metal round cutting tip located at the distal most end of the device with a cannulation for bone material to enter	Metal round cutting tip located at the distal most end of the device with a cannulation for bone material to enter	The cutting tips are identical. There are no differences.
Cutting Mechanism	Manual hand driven actuation of cutting tip to cut, scrape and carve cancellous bone	Manual hand driven actuation of cutting tip to cut, scrape and carve cancellous bone	The cutting mechanisms are identical. There are no differences.

Table 5.1: continued

Feature	**Proposed Device - Avitus® Bone Harvester**	**Predicate Device - Avitus® Bone Harvester (K170539)**	**Comments on Similarities and Differences**
Hollow Connection Between Handle and Cutting Tip	Yes - Rigid	Yes - Rigid	The connections between the handle and cutting tip are identical. There are no differences.
Power Source	None	None	The power sources are identical in that there are none. There are no differences.
Collection Mechanism	Active suction aspirates and pulls the bone graft into the bone graft reservoir	Active suction aspirates and pulls the bone graft into the bone graft reservoir	The collection mechanisms are identical. There are no differences.
Filter	Filter in lid prevents collected material from going into the suction system.	Filter in lid prevents collected material from going into the suction system	The locations and purposes of the filter are identical. There are no differences.
Filter Insert	Filter Insert is included	Filter Insert is included	The filter inserts are identical. There are no differences.
Material Retrieval	Material can be removed from reservoir by unscrewing the cap and tapping out the material or scooping out with an osteotome or other tool	Material can be removed from reservoir by unscrewing the cap and tapping out the material or scooping out with an osteotome or other tool	The material retrieval methods are identical. There are no differences.
Material Retrieval Using the Filter Insert	The removable Filter Insert can be used to pull out the collected material from inside the bone graft reservoir.	The removable Filter Insert can be used to pull out the collected material from inside the bone graft reservoir.	The methods of retrieving material using the filter insert are identical. There are no differences.
Anatomical Site	Boney region that contains a cancellous reservoir or infected, necrotic or diseased cancellous bone	Boney region that contains a cancellous reservoir	The anatomical sites are identical. The differences are related to the proposed indication for use.

Table 5.1: continued

Feature	**Proposed Device - Avitus® Bone Harvester**	**Predicate Device - Avitus® Bone Harvester (K170539)**	**Comments on Similarities and Differences**
Sterilization	EtO with SAL of 10^{-6}	EtO with SAL of 10^{-6}	The sterilization methods and SALs are identical. There are no differences.
Packaging	Tyvek covered tray with insert	Tyvek covered tray with insert	The packaging design and configurations are identical. There are no differences.
Radiopaque	Yes	Yes	Because the materials of construction are identical, the radiopaque characteristics are identical. There are no differences.
Material - Cutting Tip	Stainless Steel	Stainless Steel	The cutting tip materials of construction are identical. There are no differences.
Material - Hollow Shaft	Stainless Steel	Stainless Steel	The hollow shaft materials of construction are identical. There are no differences.
Material - Plastic Components	Rigid, translucent thermoplastic polymer	Rigid, translucent thermoplastic polymer	The plastic components materials of construction are identical. There are no differences.
Reusable/Disposable	Disposable	Disposable	The devices are disposable. There are no differences.
Depth Markings	Yes	Yes	The depth markings are identical. There are no differences.

Table 5.1: continued

Feature	**Proposed Device - Avitus® Bone Harvester**	**Predicate Device - Avitus® Bone Harvester (K170539)**	**Comments on Similarities and Differences**
Biocompatibility	The device is manufactured from materials that have been evaluated for biocompatibility for their intended patient contact profile according to ISO 10993-1	The device is manufactured from materials that have been evaluated for biocompatibility for their intended patient contact profile according to ISO 10993-1	The materials of construction are identical. There are no differences, therefore, that will impact biocompatibility.
Operating Suction Range	150mmHg – 300mmHg	150mmHg - 300mmHg	The operating suction ranges are identical. There are no differences.

5.10 Non-Clinical Testing

Non-clinical testing was not conducted in association with this submission.

5.11 Biocompatibility

The proposed Avitus® Bone Harvester (Avitus Orthopaedics, Inc.) was not subject to new biocompatibility testing because there are no new materials associated with this submission. Biocompatibility was conducted in association with prior submissions.

5.12 Clinical Testing

No clinical studies were conducted in association with this submission.

5.13 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 device.