June 26, 2023

Avitus Orthopaedics, Inc.
% Robert Mclain
Sr. Quality and Regulatory Affairs Consultant
Keystone Regulatory Services, LLC
324 E. Main Street
Leola, Pennsylvania 17540

Re: K230492
Trade/Device Name: Avitus® Precision Autograft Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: May 4, 2023
Received: May 4, 2023

Dear Robert 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.26 15:57:56 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230492

Device Name
Avitus® Precision Autograft Delivery System

Indications for Use *(Describe)*
The Avitus® Precision Autograft Delivery System is intended to be used for the delivery of autograft or hydrated allograft bone graft material to an orthopaedic surgical site.

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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510(k) Summary - K230492

Avitus Orthopaedics, Inc.
Avitus Precision Autograft Delivery System

Robert McLain

Sr. Quality and Regulatory Affairs Consultant

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June 12, 2023

Section 1

510(k) Summary

1.1 Submission Owner and Correspondent

Submission Owner

Avitus Orthopaedics, Inc.
6 Armstrong Rd., Suite 107
Shelton, CT 06484 USA
Contact: Maxim Budyansky
Phone: 860-372-7213
Email: maxim@avitusortho.com

Submission Correspondent

Keystone Regulatory Services, LLC
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Leola, PA 17540
Contact: Robert McLain
Phone: 717-656-9656
E-Mail: rob.mclain@keystoneregulatory.com

1.2 Date Summary Prepared

June 12, 2023

1.3 Device Trade Name

Avitus Precision Autograft Delivery System

1.4 Device Common Name

Piston syringe.

1.5 Device Classification Name

Syringe, Piston Classified as Class 2 at 21 CFR 880.5860, product code FMF.

1.6 Predicate Device

The Spinal Surgical Strategies, LLC Bi-Portal Bone Graft Delivery Device cleared under K142661.

1.7 Description of the Device

The Avitus Precision Autograft Delivery System is designed to deliver bone autograft or hydrated allograft material to an orthopaedic surgical site. The device delivers approximately up to 0.5cc of bone graft material per reloadable cartridge. Each system comes with the following:

- **2 x Graft Cartridge** - Features a graft channel, latching lid, and connection points to the Delivery Cannula and Threaded Delivery Plunger.
- **1 x Bone Loading Scoop Accessory** - Used to add graft to the Graft Cartridge channel.
- **1 x Bone Packer Accessory** - Used to compress graft into the Graft Cartridge channel.
- **1 x Straight Delivery Cannula** - Features a hub, which connects to a loaded Graft Cartridge, and straight-tipped cannula, through which graft material is delivered to the orthopaedic surgical site.
- **1 x Angled Delivery Cannula** - Features a hub, which connects a loaded Graft Cartridge, and angle-tipped cannula, through which graft material is delivered laterally to the orthopaedic surgical site.
- **1 x Threaded Delivery Plunger** - Features a plunger rod, knob, and threads. During graft delivery, the rod is depressed into the Graft Cartridge until the Plunger's threads engage with the Cartridge. This action transfers graft material into the Cannula. With the threads engaged, the user twists the Plunger knob to deliver a controlled volume of graft to the orthopaedic surgical site.

1.8 Indications for Use

The Avitus Precision Autograft Delivery System is intended to be used for the delivery of autograft or hydrated allograft bone graft material to an orthopaedic surgical site.

1.9 Technological Characteristics

Table 1.1 compares the technological characteristics of the proposed Avitus Precision Autograft Delivery System and the predicate Bi-Portal Bone Graft Delivery Device.

Table 1.1: Device Comparison

Feature	**Proposed Device - Avitus Precision Autograft Delivery System**	**Predicate Device - Bi-Portal Bone Graft Delivery Device (K142661)**
Product Code	FMF; Syringe, Piston	FMF; Syringe, Piston
Classification and Regulation	880.5860	880.5860
Indication for Use	Intended to be used for the delivery of bone autograft or hydrated allograft.	Intended to be used for the delivery of bone autograft or hydrated allograft.
Materials	Biocompatible Polycarbonate (Graft Cartridge, Cannula, Plunger, Pack tool, Bone Scoop Accessory) Biocompatible Stainless Steel (Cannula and Plunger)	Biocompatible Plastics (Entire Device)
Mechanism of Operation	Graft material dispersed from device tip by depressing the plunger. Plunger is threaded and is twisted clockwise to disperse graft material.	Graft material dispersed from device tip by depressing the plunger.
Recommended Graft Volume	Approximately up to 0.5cc per Cartridge	Up to 4.0cc in Barrel
Bone Graft Exit Hole Configuration	Single cannula endhole; 3.4mm diameter	Two sideholes; 5.6mm x 14.8mm
Sterilization Method	Ethylene Oxide	Ethylene Oxide

This section contains a comparison of technological characteristics of the Avitus Precision Autograft Delivery System and the predicate Bi-Portal Bone Graft Delivery Device and, where there are differences, provides an explanation of why there is no negative impact on substantial equivalence.

Materials

Both the Avitus Precision Autograft Delivery System and the predicate K142661 Bi-Portal Bone Graft Delivery Device are made of biocompatible plastic materials. All elements of the Avitus Precision Autograft Delivery System are composed of polycarbonate with the sole exception of the cannula and plunger components, which contain biocompatible stainless steel in addition to polycarbonate. The polycarbonate and stainless steel materials which make up the Avitus Precision Autograft Delivery System are identical to the polycarbonate and stainless steel materials which make up the Avitus Orthopaedics, Inc. Bone Harvester devices (K152474). Similarities in Avitus Precision Autograft Delivery System and Avitus Bone Harvester device scale, manufacturing methods, and intended clinical use environment indicate that materials will not negatively impact the overall use and function of the new device. Biocompatibility has been demonstrated with the uti-

lization of identical materials and processes to the materials found in the Avitus Orthopaedics, Inc. Bone Harvester devices, therefore, there is no negative impact on product safety or effectiveness.

Mechanism of Operation

The predicate K142661 Bi-Portal Bone Graft Delivery Device deploys bone autograft or hydrated allograft when the user depresses the Threaded Delivery Plunger into the Cannula. The Avitus Precision Autograft Delivery System deploys bone autograft or hydrated allograft using a two stage deployment process. First, user depresses the Threaded Delivery Plunger into the Graft Cartridge until the Plunger's back-end threads engage with the Graft Cartridge, moving bone graft material into the Cannula. Next, the user turns the Threaded Delivery Plunger to deploy the desired volume of bone graft material from the Cannula. Despite this additional feature, which provides the user with precise control over the deployed volume of bone graft, the Avitus Precision Autograft Delivery System and the predicate K142661 Bi-Portal Bone Graft Delivery Device share the same basic mechanism of action. The addition of the threaded mechanism in the Avitus Precision Autograft Delivery System does not negatively impact product safety or effectiveness.

Recommended Graft Volume

The predicate K142661 Bi-Portal Bone Graft Delivery Device can accommodate up to 4.0 cc of hydrated allograft or autograft material in its syringe barrel. The Avitus Precision Autograft Delivery System can accommodate approximately up to 0.5 cc of hydrated allograft or autograft material in each reloadable Graft Cartridge. If more graft is required at the delivery site, the user replaces the Graft Cartridge with another loaded Graft Cartridge. This is repeated as many times as needed by opening the lid of the Graft Cartridge and reloading it after bone delivery. The Avitus Precision Autograft Delivery System and the predicate K142661 Bi-Portal Bone Graft Delivery Device are intended to deliver different volumes of graft. There is no negative impact of recommended graft volume on product safety or effectiveness because the Avitus Precision Autograft Delivery System will be utilized by clinicians who want to deliver smaller, precise volumes of graft.

Bone Graft Exit Hole Configuration

The predicate K142661 Bi-Portal Bone Graft Delivery Device deploys bone autograft or hydrated allograft through bilateral sideholes. Each sidehole measures 14.8 mm x 5.6 mm. The Avitus Precision Autograft Delivery System deploys bone autograft or hydrated allograft through a single endhole in the case of the Straight Delivery Cannula and through a single sidehole in the case of the Angled Delivery Cannula. Both Straight and Angled Delivery Cannulas have an exit hole diameter of 3.4 mm. This difference, combined with the difference in recommended graft volume, indicates that the devices are designed to deliver different volumes of graft material, however, there is no difference between the proposed and predicate devices in terms of function and intended purpose. The Avitus Precision Autograft Delivery System effectively delivers graft material. This has been demonstrated in performance testing. There is no negative impact of the difference in bone graft exit hole configuration on product safety or effectiveness.

1.10 Non-Clinical Testing

Avitus Orthopaedics, Inc. performed worst-case non-clinical testing in which the Avitus Precision Autograft Delivery System was used to deliver cadaveric bone graft material. Testing found that the Avitus Precision Autograft Delivery System meets the reliability and confidence requirements for successful delivery and for structural integrity during normal use.

1.11 Biocompatibility

The previously-cleared Avitus Bone Harvester and the Avitus Precision Autograft Delivery System are both external communicating devices with limited tissue/bone/dentin contact (<24 hours). Per ISO 10993-1:2018 and FDA Guidance Use of International Standard ISO 10993-1, the following biocompatibility endpoints are appropriate for both devices:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

Per Attachment D of the aforementioned FDA guidance, the results of biocompatibility testing of the Avitus Bone Harvester may be applied to the subject device, considering that the material formulation, body contact, and sterilization of direct and indirect contacting components are identical and that the geometry and manufacturing processes (noting that no new plasticizers, fillers, additives, cleaning agents, mold release agents have been added to the subject device manufacturing process) of the Avitus Bone Harvester represent worst-case biocompatibility conditions.

1.12 Clinical Testing

No clinical testing was performed in association with this submission.

1.13 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 devices.