June 9, 2022

Redpoint Medical, LLC
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, QC J7V7P2
Canada

Re: K220717
Trade/Device Name: RedPoint Medical's Better Bunion System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF
Dated: March 9, 2022
Received: March 11, 2022

Dear Robert Poggie:

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,

For: Shumaya Ali, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220717

Device Name

Better Bunion System

Indications for Use *(Describe)*

The Better Bunion System is intended to be used as a surgical instrument to assist in pre-operative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies in the foot and ankle for adult and pediatric patients 12 years of age and older. Better Bunion cutting guides are intended for single use only.

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

X 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.

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510(k) SUMMARY – K220717, The Better Bunion System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of the Better Bunion System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, QC, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796
Fax Number:	(514) 901-0796
Date of Submission:	March 9, 2022

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	RedPoint Medical, LLC
Manufacturer Address:	13326 West Road, Carmel, Indiana, 46074, USA
Registration Number:	10084570
Contact Name:	James Spitler
Title:	Chief Technology Officer
Device Trade Name:	Better Bunion System
Common Name:	Patient specific orthopedic guides
Classification Name:	Orthopaedic surgical planning and instruments guide
Classification Code:	PBF
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3030.

C1. PRIMARY PREDICATE DEVICE

K163156	Materialise Surgicase Guides

C2. PREDICATE DEVICE

K211244	3D System's VSP Orthopedics System

D. DEVICE DESCRIPTION

The RedPoint Medical Better Bunion system includes single use, patient specific bone resection guides designed from DICOM files from a patients' CT scans and a surgeon's prescription. The Better Bunion system includes single use and reusable instruments to facilitate surgery. The Better Bunion patient specific bone resection guides assist the surgeon in cutting bone in the foot and ankle according to the pre-surgical plan. The guides are individually manufactured for each patient using a validated design and manufacturing process with strict procedures for transfer and conversion of patient images from DICOM files to digital models (STL files), and in turn to patient specific bone resection guides that are additively manufactured with titanium alloy conforming to ASTM F3001. The bone cutting guides are single use devices and provided clean, not sterile to the end user.

E. INTENDED USE

The Better Bunion System is intended to be used as a surgical instrument to assist in pre-operative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies in the foot and ankle for adult and pediatric patients 12 years of age and older. Better Bunion cutting guides are intended for single use only.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Better Bunion System patient specific bone resection guides have similar intended use and technological characteristics as the predicate devices, with focus on foot and ankle procedures including osteotomies of the first metatarsal for correction of hallux valgus deformities. The following points compare the similarities and differences of technological features of the subject and predicate devices.

- The indications for use for the subject device and predicate devices are similar in aiding surgeons in planning and executing patient specific, non-acute, non-joint replacing bone resections of the lower extremities. The primary differences in indications for use are the subject device is intended for osteotomy procedures in the foot and ankle while the predicate devices are generally indicated in upper and lower extremities, and for planning and performing osteotomies about the knee.
- The designs of the patient specific guides for the subject and predicate devices are based on a patient´s images and surgeon´s prescription. The design of the subject bone resection guides is limited to DICOM images from the patients CT scans.
- The subject and predicate devices use validated software for conversion of imaging data to digital models of the bones that can be used to design and manufacture patient specific instruments for guiding the resection of bone.
- The subject and predicate devices include patient specific cutting guides to aid in surgical procedures. The cutting guides of the predicate devices are made from

additively manufactured Nylon-12, while the subject device is made from additively manufactured titanium alloy conforming to ASTM F3001.

- The accuracy of the predicate and subject cutting guides were validated in simulated surgical studies.
- The subject and predicate device cutting guides are provided clean, not sterile to the end-user.
- The subject and primary predicate devices include pediatric use. The subject device is indicated for pediatric patients greater than 12 years of age that may not be fully grown; the primary predicate devices is indicated for patients 7 years of age and older. For both the subject and primary predicate devices, the physician must consider the patient pathology evolution between CT scan date and the surgery date to validate the imaging data prior to surgery. If the patient's anatomy changed since the date of imaging, the patient specific cutting guides should not be used.

G. PERFORMANCE DATA

The following summarizes performance testing and validation and verification activities for the Better Bunion system.

- Verification of fit and usability of the Better Bunion patient specific cutting guides for the Lapidus procedure, and Akin, Calcaneal, and Met-Traverse Metadductus osteotomies.
- Simulated surgeries for correction of hallux valgus deformities demonstrated the Better Bunion guides to provide a final average intermetatarsal (IM) angle of ±2° relative to plan, an IM angle of <4° for all guides, and an average deviation of 0.91° relative to plan.
- The single use and reusable instruments were determined to be biocompatible per ISO 10993-1.
- Sterilization validation with sterility assurance level (SAL) of 10^{-6} using the overkill method per AAMI/ISO 14927.

H. CONCLUSION

The Better Bunion System is substantially equivalent to the identified predicate devices based on similarities in indications for use, design, technological characteristics, and performance data presented in this 510(k) notification.