March 12, 2021

Bodycad Laboratories, Inc.
Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre Dame de L'lle Perrot, QC J7V 7P2
Canada

Re: K203697
Trade/Device Name: BC Reflex Uni™ Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: December 16, 2020
Received: December 18, 2020

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,

Ting Song, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*

K203697

Device Name

BC Reflex Uni™ Knee System

Indications for Use *(Describe)*

The patient-specific BC Reflex Uni™ is indicated for unicompartmental knee arthroplasty (UKA) in patients with advanced knee osteoarthritis (OA) of the medial compartment with evidence of adequate healthy bone to support the implanted components. Candidates for unicompartmental knee replacement include those with:
• joint impairment due to osteoarthritis or traumatic arthritis of the knee,
• varus deformity of the knee, and
• as an alternative to tibial osteotomy in patients with unicompartmental OA.
The patient-specific BC Reflex Uni™ components fit within an envelope of dimensions that are specific to each patient. The BC Reflex Uni™ femoral component and tibial baseplate are intended for cemented fixation.

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

The BC Reflex Uni™ Knee 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 BC Reflex Uni™ Knee 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 & Fax Number:	(514) 901-0796
Date of Submission:	March 4, 2021

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Laboratories Bodycad, Inc.
Manufacturer Address:	2035 rue du Haut-Bord, Quebec, QC, G1N 4R7, Canada
Registration Number:	3012086398
Contact Name:	Nadine Adia
Title:	Specialist, Regulatory Affairs
Device Trade Name:	BC Reflex Uni™ Knee System
Device Common Name:	Unicondylar knee device
Classification Name:	knee joint femorotibial metal/polymer non-constrained, cemented
Classification Code:	HSX – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR section 888.3520

C1. PRIMARY PREDICATE DEVICE

K191996	BC Reflex Uni™ Knee System (primary predicate device)

C2. PREDICATE AND REFERENCE DEVICES

K191150	BC Reflex Uni™ Knee System (predicate device)
K181302, K163700	Bodycad Unicompartmental Knee System (reference device)
K193614	Fine Osteotomy Around the Knee (reference device)

D. DEVICE DESCRIPTION

The BC Reflex Uni™ Knee System is a patient-specific unicompartmental knee system that consists of femoral and tibial implants for replacement of the medial tibiofemoral compartment of the knee. The patient-specific femoral and tibial implants and single-use instruments are manufactured from CAD and CAM files generated from Bodycad software, which are based on MRI or CT images of the patient's knee and input from the surgeon. The BC Reflex Uni™ is for cemented use only and is sterilized by gamma radiation.

The subject device of this 510(k) is the same as the primary predicate device. The purpose of this Special 510(k) Device Modification is to notify the FDA of minor changes to the design and contents of the patient specific kits and reusable instruments for the BC Reflex Uni™ Knee System.

Materials: Wrought Cobalt-28Chromium-6Molybdenum Alloy (CoCrMo; ASTM F1537-11) for the femoral component, wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (Ti6Al4V ELI; ASTM F136-13) for the tibial baseplate and locking pin, Ultra-High-Molecular-Weight Polyethylene (UHMWPE; F648-14) for the tibial insert.

E. INTENDED USE

The patient-specific BC Reflex Uni™ is indicated for unicompartmental knee arthroplasty (UKA) in patients with advanced knee osteoarthritis (OA) of the medial compartment with evidence of adequate healthy bone to support the implanted components. Candidates for unicompartmental knee replacement include those with:

• joint impairment due to osteoarthritis or traumatic arthritis of the knee,
• varus deformity of the knee, and
• as an alternative to tibial osteotomy in patients with unicompartmental OA.

The patient-specific BC Reflex Uni™ components fit within an envelope of dimensions that are specific to each patient. The BC Reflex Uni™ femoral component and tibial baseplate are intended for cemented fixation.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The BC Reflex Uni™ Knee System described in this 510(k) notification is essentially the same device as the primary predicate device cleared by FDA in K191996 and the predicate device described in K191150. Most technological characteristics remain unchanged from the two predicate and subject devices. Commonalities between the subject and predicate devices are:

- Patient specific knee implants and instruments are designed and manufactured from MRI or CT images of the patient's knee.
- Patient specific components including CoCr femoral and Ti alloy tibial implants, polyethylene inserts, and locking pin for assembly of the tibial insert and baseplate, and single use additively manufactured Nylon-12 bone models and guides to facilitate surgery.
- The clinical indications for use are identical.
- The CoCrMo, titanium alloy, UHWMPE, and Nylon-12 materials are identical.
- The manufacturing processes are identical.
- Single use, patient specific kit provided sterile with SAL of 10^{-6}.

The minor differences between the subject and predicate devices are:

- Updates to Bodycad software to improve efficiency in design and manufacture of patient specific components of the BC Reflex Uni™ Knee System.
- Added option in patient specific design process to use validated Bodycad software, or previously validated off the shelf software.
- Minor design updates to implant components to improve clarity in design specifications, manufacturability, and/or usability per the intended use.
- Updates to the single use / disposable instruments and the reusable instrument kit to improve workflow in surgery and improve function, in keeping with intended / indications for use for the subject and predicated device (same).

The minor changes to the BC Reflex Uni™ Knee System do not raise new issues of safety or effectiveness. The information presented in this Special 510(k) Device Modification demonstrates substantial equivalence of the subject and predicate device.

G. PERFORMANCE DATA

The following verification and validation (V&V) activities were performed:

- Software V&V accounting for all changes per Bodycad procedures, which are the same procedures presented to FDA previously for the predicate and reference devices.
- Risk analysis and design control review confirming no new or changed risks relative to the indications for use and efficacy of product.
- Verification testing of usability of updated devices.

The results of V&V testing and engineering review, risk analysis, and design control activities demonstrated substantial equivalence of the subject and predicate BC Reflex Uni™ Knee System.

H. CONCLUSION

The BC Reflex Uni™ subject components of 510(k) notification are substantially equivalent and share the same intended use as the predicate devices cleared in K191150 and K191996.