October 12, 2021

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

Re: K212307
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: August 12, 2021
Received: August 13, 2021

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, Ph.D., R.A.C.
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)*

K212307

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

Traditional 510(k) Notification for the BC Reflex Uni™ Knee System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 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:	August 12, 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

K203697	Bodycad Inc. BC Reflex Uni™ Knee System

C2. PREDICATE DEVICE

K191150	Bodycad Inc. BC Reflex Uni™ Knee System (Tibia)

C3. REFERENCE DEVICES

K033363	Zimmer Unicompartmental Knee System (ZUK)
K163700	Bodycad Unicompartmental Knee System

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 to a SAL of 10^{-6}.

The primary reasons for this 510(k) notification are to notify the FDA: (1) that the tibial insert will be manufactured from vitamin E stabilized and 100 kGy crosslinked UHMWPE (Vit-E HXLPE), (2) that a 5 mm thick tibial insert was added as a thickness option, and (3) of minor design updates to the implants and single use instruments.

Materials: Wrought Cobalt-28Chromium-6Molybdenum Alloy (ASTM F1537-11) for the femoral component, wrought Titanium-6Aluminum-4Vanadium ELI Alloy (Ti6Al4V ELI; ASTM F136-13) for the tibial baseplate and locking pin, Ultra-High-Molecular-Weight Polyethylene (UHMWPE) or Vit-E HXLPE 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) is essentially the same device as the primary predicate device cleared in K203697. The technological characteristics that remain the same for the BC Reflex Uni™ Knee System are:

- Patient specific knee implants and instruments that are designed and manufactured from MRI or CT images of the patient's knee. The implant components include CoCr femoral and Ti alloy tibial implants, polyethylene inserts, a Ti alloy locking pin, and single use additively manufactured Nylon-12 bone models and cutting guides.
- The clinical indications for use and the intended use are identical.
- The CoCrMo, titanium alloy, and Nylon-12 materials are identical.
- The manufacturing processes are the same.
- The size envelope for the tibial and femoral components are the same.
- Single use, patient specific kits are provided sterile with SAL of 10^{-6}.

The similarities in technological characteristics for the subject BC Reflex Uni Knee System and the ZUK reference device are:

- The minimum thickness of the tibial insert (5 mm) is the same for the reference ZUK and subject BC Reflex Uni Knee System, and both are unconstrained articulation.

The primary differences between the subject and primary predicate BC Reflex Uni devices are:

- Vitamin E stabilized and 100 kGy crosslinked UHMWPE (Vit-E HXLPE) material was added as an option for manufacture of the tibial inserts.
- A new thickness tibial insert (5 mm) was added to the BC Reflex Uni Knee System.
- Minor design updates were made to the femoral and tibial implant components to increase flexibility in sizing and fit to the patient, in keeping with original design envelope for the primary predicate and reference ZUK devices.
- Updates to the single use instruments were made to facilitate surgery with the new thickness tibial insert and improve usability.

G. PERFORMANCE DATA

The following performance testing and verification activities were performed:

- Wear testing per ISO 14243-3 and ISO 14243-2 of worst-case subject BC Reflex Uni and reference ZUK tibial inserts made of standard UHMWPE (non-vitamin E, 25-40 kGy gamma radiation) and Vit-E HXLPE. The results showed less wear of the Vit-E HXLPE inserts relative to the standard UHMWPE inserts, and no difference in wear rate between the 5 and 6 mm tibial inserts made from standard UHMWPE.
- Finite element analysis verified substantial equivalence of contact stress of the 5 and 6 mm tibial inserts for the subject, primary predicate, and reference devices.
- Verification of substantial equivalence and/or superiority of performance characteristics and materials properties of the Vit-E HXLPE relative to standard UHMWPE for: density per ASTM F648 and D792, mechanical properties per ASTM F648, F2759, D695, F2183, melting point, crystallinity, and enthalpy of fusion per ASTM F2625, swell ratio and crosslink density per ASTM F2214, fatigue crack propagation and coefficient per ASTM E647, oxidation challenge per ASTM F2003 and analysis per ASTM F2102, ESR testing for residual free radical content, and Transvinylene index (TVI) per ASTM F2381.
- Testing and verification of integrity of the locking mechanism of a 5mm thick tibial insert.
- Software V&V accounting for all changes per Bodycad standard operating procedures.
- Risk analysis and design control review confirming no new or changed risks relative to the indications for use and efficacy of the subject device.

H. CONCLUSION

The results of performance testing, V&V analyses, and engineering review demonstrated substantial equivalence of the subject BC Reflex Uni™ Knee System to the primary predicate, predicate, and reference devices cited in this 510(k) notification.