December 5, 2019

Bodycad Laboratories, Inc.
℅ Robert Poggie
President
BioVera Inc.
65 Promenade Saint Louis
Notre-Dame-de-l'Ile-Perrot, j7v 7p2 CANADA

Re: K191996
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: September 6, 2019
Received: September 9, 2019

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
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191996

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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, Quebec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796
Fax Number:	(514) 901-0796
Date of Submission:	July 25, 2019

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Bodycad Laboratories Inc.
Manufacturer Address:	2035 rue du Haut-Bord, Quebec, Quebec, G1N 4R7, Canada
Registration Number:	3012086398
Contact Name:	Guy Sevigny
Title:	Director, 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. PREDICATE DEVICE

K163700	**Bodycad Unicompartmental Knee System (BUKS)**
K181302	**Bodycad Unicompartmental Knee System (BUKS)**
K191150	**Bodycad Unicompartmental Knee System (BUKS)**

C2. REFERENCE DEVICE

K033363	**Zimmer Unicompartmental Knee System (ZUK)**

D. DEVICE DESCRIPTION

The BC Reflex Uni™ Knee System is a patient-specific prosthesis that consists of femoral and tibial implants for replacement of the medial tibiofemoral compartment of the knee. The patient-specific femoral and tibial components and single-use cutting guides are manufactured from CAD and CAM files generated from Bodycad and off the shelf 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 of this 510(k) is an updated / new design of the femoral component and instruments for implantation, relative to the femoral component described in K163700 and K181302 for the predicate BUKS.

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. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The BC Reflex Uni™ described in this 510(k) notification has the same intended use and general technological features as the predicate devices cleared by FDA in K163700 and K181302 (BUKS). The design modifications to the femoral component include elimination of the screw for ancillary fixation, replacing the resurfacing geometry of the bone-cement surface of the femoral component with a more traditional angular box geometry, and changes to instrumentation associated with the change in design of the femoral component. Comparison of the design features of the BC Reflex Uni™ femoral component with those of the original BUKS femoral component (K163700, K181302) and the ZUK reference device, and results of performance and simulated-surgery verification testing of the subject BC Reflex Uni™ Knee System has established substantial equivalence of the subject, predicate, and reference devices.

G. PERFORMANCE DATA

The following performance tests were performed for the BC Reflex Uni™ Knee System:

- Femoral component fatigue strength per ASTM WK51649 – Standard Test Method for Fatigue Testing of Total Knee Femoral Components under Closing Conditions.
- Surgeon-user verification cadaver surgeries with the BC Reflex Uni™ femoral component and instruments.

The results of performance testing demonstrated substantial equivalence of the subject, predicate, and reference devices.

H. CONCLUSION

The BC Reflex Uni™ subject components of this 510(k) notification are substantially equivalent and share the same intended use as the predicate BUKS cleared in K163700, K181302, and K191150, and the reference device (ZUK, K033363).