August 20, 2021

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

Re: K211895
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: June 16, 2021
Received: June 21, 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.
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)*

K211895

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.

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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, Province of Quebec, J7V7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone & Fax Number:	(514) 901-0796
Date of Submission:	June 16, 2021

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Bodycad Laboratories 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	BC Reflex Uni™ Knee System (primary predicate device)

C2. REFERENCE DEVICES

K210252	ConforMIS iTotal iDentity CR and PS Knee Systems
K102330	STERIS V-PRO maX

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 that are based on MRI or CT images of the patient's knee and surgeon input.

The main purpose of this traditional 510(k) Notification is to advise the FDA of Bodycad's use of low temperature hydrogen peroxide sterilization (VH2O2) for terminal sterilization of BC Reflex Uni patient kits. Secondary purposes of this 510(k) notification are validation of cleaning and steam sterilization of BC Reflex Uni Knee System components in case of breach of sterile packaging in transit or handling, and minor design updates to single use instrumentation and software. BC Reflex Uni components are supplied sterile (SAL of 10^{-6} via gamma radiation or VH2O2).

Materials: Femoral component: ASTM F1537-11 wrought CoCrMo. Tibial baseplate and locking pin: ASTM F136 titanium alloy (ELI). Tibial insert: F648-14 UHMWPE.

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 as the primary predicate device cleared by FDA in K203697. Commonalities shared by both the subject and primary predicate devices include:

- Patient specific knee implants and instruments designed and manufactured from MRI or CT images of the patient's knee.
- Patient specific components including CoCr femoral and Ti alloy locking pin and tibial baseplate, polyethylene inserts, and single use Nylon-12 bone models and guides.
- The clinical indications for use and intended 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 differences between the subject and primary predicate devices are:

- Addition of a second option for terminal sterilization of BC Reflex Uni patient kits using low temperature vapor hydrogen peroxide sterilization (VH2O2) using the STERIS V-PRO maX (K102330).
- Addition of ability to perform one-time, point of use cleaning and steam sterilization of BC Reflex Uni components in case of breach of sterile packaging in transit or handling.
- Two minor updates to the single use instruments and two minor updates to the software to better facilitate surgical procedure and patient specific design.

G. PERFORMANCE DATA

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

- Validation of terminal sterilization with SAL of 10^{-6} for worst-case BC Reflex Uni kits using the STERIS V-PRO maX (K102330) per the applicable clauses of ISO 14937.
- Validations of shelf life, biocompatibility per ISO 10993-1, packaging per AAMI/ANSI/ISO 11607, and verification of acceptable levels of residual hydrogen peroxide per ISO 10993-17.
- Validation that BC Reflex Uni components meets pyrogen limit specifications (e.g., bacterial endotoxins test (BET), also known as the Limulus amebocyte lysate (LAL) test).
- Validation of point of use cleaning and steam sterilization applicable to BC Reflex Uni components using the partial cycle validation approach outlined in ANSI/AAMI/ISO 17665-1:2006/(R)2013, Annex D, and the validation approach outlined in ANSI/AAMI/ISO 14937:2009/(R)2013, Annex D (Approach 3).

The results of V&V testing and engineering review, risk analysis, and design control activities demonstrated no new issues affecting safety or effectiveness resulting from the new methods of cleaning and sterilization of the BC Reflex Uni Knee System and the two minor updates to the single use instruments and update to software.

H. CONCLUSION

The results of V&V testing and engineering review, risk analysis, and design control activities demonstrated substantial equivalence of the subject BC Reflex Uni Knee System sterilized by low temperature hydrogen peroxide vapor to the primary predicate device, the BC Reflex Uni Knee System sterilized by gamma radiation.