October 8, 2019

% Robert Poggie
President
BioVera Inc.
65 Promenade Saint Louis
Notre-Dame-de-l'Ile-Perrot, QC, J7V 7P2 Canada

Re: K191150
Trade/Device Name: Bodycad Unicompartmental 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 4, 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2019.10.08 11:44:53 -04'00'

For 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)*

K191150

Device Name

Bodycad Unicompartmental Knee System

Indications for Use *(Describe)*

The patient-specific Bodycad Unicompartmental Knee System (Bodycad UKS) 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 Bodycad UKS components fit within an envelope of dimensions that are specific to each patient. The Bodycad UKS femoral component and tibial baseplate are intended for cemented fixation. A Bodycad screw must be used for fixation of the femoral component.

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

Bodycad Unicompartmental 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 Bodycad Unicompartmental 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:	April 29, 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:	Bodycad Unicompartmental 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)**

C2. REFERENCE DEVICE

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

D. DEVICE DESCRIPTION

The Bodycad Unicompartmental Knee System (BUKS) 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 software, which are based on MRI or CT images of the patient's knee and input from the surgeon. The BUKS is for cemented use only and is sterilized by gamma radiation.

The subject of this 510(k) notification is a line extension and design update that includes a new tibial baseplate that is compatible with the BUKS system (K163700, K181302) and instruments that are compatible with the new tibial baseplate.

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

E. INTENDED USE

The patient-specific Bodycad Unicompartmental Knee System (Bodycad UKS) 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 Bodycad UKS components fit within an envelope of dimensions that are specific to each patient. The Bodycad UKS femoral component and tibial baseplate are intended for cemented fixation. A Bodycad screw must be used for fixation of the femoral component.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The BUKS 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 tibial baseplate cleared in K163700 include: Reduced thickness of the base plate (UHMWPE inset sliding and upper rails, cement pocket, and baseplate), reduced diameter of the locking pin and corresponding reduction of the diameter of hole for locking pin, increased diameter and redesign of fixation posts, addition of a medial fixation fin, and elimination of the flange and screw-hole for ancillary fixation. Other design changes relative to BUKS components cleared in K163700 is a single-use instrument for preparation of the holes and slot for the new fixation posts and fin. Comparison of the design features of the new BUKS tibial baseplate with those of the original BUKS baseplate (K163700, K181302) and the ZUK reference device, and results of performance testing of the subject tibial base plate and tibial insert assembly have established substantial equivalence of the subject, predicate, and reference devices.

G. PERFORMANCE DATA

The following tests were performed for establishing substantial equivalence of subject, predicate, and reference devices:

- Tibial baseplate fatigue strength per 3-point bend method as described in ASTM F3140-17, Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements, and ASTM F1800-12, Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements.
- Resistance to dislodgement of the polyethylene insert in both the as-manufactured and post cyclic fatigue conditions.
- Pull-out force for the locking pin at time-zero, as manufactured, and post cyclic fatigue.
- Surgeon-user validation, simulated surgeries with the new tibial baseplate, locking pin, insert, and associated instruments.

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

H. CONCLUSION

The subject components of this line extension to the BUKS are substantially equivalent and share the same intended use as the predicate BUKS cleared in K163700 and K181302, and the reference device (K033363).