January 17, 2019

Bodycad Laboratories Inc.
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'Ile-Perrot, Quebec, J7V 7P2, CA

Re: K181302
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: December 19, 2018
Received: December 26, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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: 2019.01.17 15:15:52 -05'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181302

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. The Bodycad screws must be used for fixation of the femoral and tibial components.

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

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, Québec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796; (514) 349-7226
Fax Number:	(514) 901-0796
Date of Submission:	December 19, 2018

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:	Guy Sévigny
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

C. PREDICATE DEVICE

K163700	**The Bodycad Unicompartmental Knee System (Bodycad UKS)**

D. DEVICE DESCRIPTION

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

Materials: CoCrMo (ASTM F1537-11) for the femoral component, Ti6Al4V ELI (ASTM F136-13) for the tibial component, UHMWPE (F648-14) for the tibial insert

E. INDICATIONS FOR 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. The Bodycad screws must be used for fixation of the femoral and tibial components.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Bodycad UKS is a patient-specific unicompartmental knee system comprised of two groups of components: (1) prosthetic components / implants, and (2) instrument components. The first group includes a series of devices that are implanted in the patient's body while the second group includes instruments that facilitate implantation of the components. Both groups of components are manufactured to match the patient's anatomy based on MRI or CT images. The implants and instruments are packaged and terminally sterilized with gamma radiation to a sterility assurance level of 10^{-6}. The technological characteristics and manufacturing methods of the predicate and subject devices are identical.

G. PERFORMANCE DATA

Validation testing was performed for CT and MRI imaging modalities and demonstrated substantial equivalence of the 3D digital bone models being equivalent for data extracted from CT and MR images.

H. CONCLUSION

The results of validation testing demonstrated substantial equivalence of CT and MR imaging modalities for the Bodycad Unicompartmental Knee System.