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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K163700

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.

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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: February 24, 2017

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: Marc Chaunet
Title: Vice-President, Regulatory Affairs and Quality
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 DEVICES

K033363  Zimmer Unicompartmental Knee System (ZUK)
K043570  ConforMIS Unicondylar Knee System
K132640  ConforMIS iUni Unicondylar Knee Replacement System
K133811  Mako Restoris Unicondylar Knee System
K123380  Smith & Nephew STRIDE Unicondylar Knee
K081351, K102069  Smith & Nephew Journey UNI
C2. REFERENCE DEVICES
K132788 Medacta MySpine Pedicle Screw Placement Guides
K082358 Smith & Nephew Patient Matched Cutting Blocks

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 images of the patient's knee and input from the surgeon. The femoral component is fabricated from wrought Cobalt-Chrome alloy (CoCr) with a centrally located peg and provision for ancillary fixation with a CoCr bone screw. The tibial implant consists of a Titanium (Ti) alloy baseplate with one to three posterior spikes and provision for ancillary fixation with a Tit alloy bone screw. The polyethylene insert is fabricated from Ultra-High-Molecular-Weight Polyethylene (UHMWPE), compression molded and machined GUR 1020. The tibial-femoral articulation is an unconstrained design. This device is for cemented use.

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 images.
The femoral component is made of CoCr with a central peg and provision for ancillary fixation with a CoCr screw. The design of the femoral component is based on the shape of the femoral condyle of the patient which is obtained from MRI images. The level of coverage of the femur is
predetermined by the surgeon based on location and extent of osteoarthritis. The Bodycad UKS is patient specific, with maximum and minimum values assigned to critical dimensions such as anterior-posterior maximum box width, maximum anterior-posterior width, and minimum and maximum radii in the sagittal curve.

The tibial implant consists of a Ti alloy baseplate with one to three posterior spikes and provision for ancillary fixation with a Ti alloy bone screw. The tibial implant size and shape is based on 3D modeling of the knee joint obtained from the patient’s MRI. The tibial baseplate possesses a locking mechanism and pin to retain and secure the UHMWPE tibial insert. Maximum and minimum size values have been assigned to the tibial implants. The polyethylene insert is fabricated from UHMWPE conforming to ASTM F648-14. The tibial-femoral articulation is an unconstrained design.

The Bodycad UKS includes two patient-specific cutting guides for the femur and tibia that are single-use instruments. The cutting guides are designed to fit the patient’s anatomy, per 3D modeling of the patient’s knee and the design of the prosthesis. The cutting guides are made of polyamide-12 (Nylon 12). The patient-specific implant components and cutting guides are manufactured from CAD – CAM models created from the patient’s MRIs and input from the surgeon, using Bodycad proprietary software. This software, and off-the-shelf software, were validated per the FDA guidance document “Guidance for the content of premarket submissions for software contained in medical devices”. The system is for cemented use only.

Comparison of the technological characteristics of the Bodycad UKS to those of the predicate devices show the Bodycad UKS to be substantially equivalent to the cited predicate devices.

G. PERFORMANCE DATA

Characterization of the Bodycad UKS was performed per the FDA Guidance Document entitled “Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA” and publicly available information regarding the predicated devices and recommendation from FDA in pre-submission Q150560. The components of the Bodycad UKS were subjected to the following tests:

- Tibial baseplate fatigue strength per 3-point bend method as described by Yildirim, (Society for Biomaterials, SFB2014 Conference Abstract #417), and currently under review by ASTM subcommittee F04.22, Work Item WK45235 as a new draft standard for cyclic fatigue testing on UKR trays, and ASTM F1800-12”, as recommended by FDA in pre-sub Q150560 and subsequent communication with the Agency (K153418/S001).
- Range of Motion (ROM) per ASTM F2083-12, thru 120 degrees. Flexion- extension, internal-external rotation, varus-valgus, translation (AP, ML); ROM was tested to maximum (impingement).
- Constraint testing / analysis per ASTM F1223-14. Contact area and stress 0, 15, 90, 120 degrees of flexion.
• Fatigue strength of the femoral component for worst-case loading and size (largest).
• Contact pressure / stress and area of tibiofemoral articulation of UHMWPE inserts per ASTM F2083-12.
• Resistance to dislodgement of the tibial insert; i.e. strength of locking mechanism.
• Evaluation of contact stress (magnitude and location) on the polymer tibial insert bearing surface using computational finite element method, and verified with physical testing of components.
• Evaluation of bone screw trajectories and effect on cemented implantation.
• Characterization of UHMWPE inserts for conformance to ASTM F648-14.
• Cadaver laboratory testing and evaluation of: Surgical technique and implant fit to patient-specific plan and final seating and fit of cemented implants with ancillary screws.
• Evaluation of the effectiveness of screws in initial fixation with bone cement.
• Cadaver evaluation of the strength of the tibial and femoral fixations screws.
• Evaluation of the single-use cutting guides for cleanliness, shipping, dimensional, biocompatibility, pyrogenicity, stability, and resistance to wear.
• Implant components and single use cutting guides that comprise the BUKS kit were evaluated for pyrogenicity using the bacterial endotoxins test (BET, e.g., LAL test).

The results of testing showed:
• The fatigue strength of the Bodycad UKS tibial and femoral components withstood worst-case physiological loading.
• ROM testing showed the Bodycad UKS to possess substantially equivalent motion characteristics as the predicate devices and reported in the scientific literature for UKA devices.
• Comparison of the tibial and femoral articular surfaces of the Bodycad UKS to the predicate devices, and analyses of constraint, ROM, and contact stress/area of the Bodycad UKS, established substantial equivalence to the predicate devices.
• The screw trajectories for the femur and tibia were within the envelope of bone and not at risk of perforation of bony surfaces. Evaluation and testing of femoral and tibial ancillary fixation in cadaver knees and Saw Bones demonstrated substantial equivalence to the predicate and reference devices.
• The UHMWPE material used in the manufacture of the tibial inserts was found to be in conformance with ASTM F648.
• Cadaver laboratory testing and evaluation of surgical fit to the plan (surgeon input and software) showed the implants to fit and surgery to be completed to the patient-specific, prescribed plan. The cadaver studies performed for the Bodycad UKS showed without exception that the patient specific implants and instruments to fit as planned by the surgeons and Bodycad software.
• The single-use cutting guides met the performance criteria and were validated for their intended use.
• The bacterial endotoxins test (BET), also known as the Limulus Amebocyte Lysate (LAL) test, showed the implant components and single-use cutting guides of the BUKS kit to meet established limits for endotoxin units.
H. CONCLUSION

The Bodycad Unicompartmental Knee System is substantially equivalent to the identified predicate and reference devices based on the performance testing data presented here and validations of the software used to fabricate the patient-specific implants and cutting guides.