April 7, 2020

Optimotion Implants, LLC
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre Dame de Lile Perrot, J7V 7P2 CA

Re: K191084
Trade/Device Name: The Optimotion Blue Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH, MBH
Dated: March 31, 2020
Received: April 6, 2020

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., R.A.C.
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)*
K191084

Device Name

The Optimotion Blue Total Knee System

Indications for Use *(Describe)*

• Painful, disabling joint disease of the knee resulting from; noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
• Post-traumatic loss of knee joint configurations and function.
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
• Revision of previous unsuccessful knee replacement or other procedure.
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques.

Optimotion™ Blue Porous Tibial Baseplate components are indicated for Cemented or Cementless use. The Optimotion™ Blue Porous CR Femoral components are indicated for Cemented or Cementless use. The Optimotion™ Blue CEMENTED CR Femoral and CEMENTED Tibial Baseplate components are indicated for cemented use only.

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 for the Optimotion™ Blue Total 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 Optimotion™ Blue Total Knee System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'lle-Perrot, Province of Quebec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796
Fax Number:	(514) 901-0796
Date of Submission:	November 6, 2019

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Optimotion Implants, LLC
Manufacturer Address:	3505 Lake Lynda Drive, Bldg 300, Suite #206 Orlando, Florida 32817
Registration Number:	Not registered at this time
Contact Name:	Dan Justin
Title:	CEO
Device Trade Name:	Optimotion™ Blue Total Knee System
Device Common Name:	Total Knee
Classification Name:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (CFR 888.3560) Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (CFR 888.3565)
Classification Code:	OIY, JWH, and MBH
Classification Panel:	Orthopedic
Regulation Number:	21 CFR sections 888.3560 and 888.3565

C1. PREDICATE DEVICES

K160515	Consensus Orthopedics PS2 Knee System
K123486	Stryker Triathion® Tritanium Tibial Baseplates
K051380	Stryker Triathlon Total Knee System

C2. REFERENCE DEVICES

K1133369	Zimmer Persona Personalized Knee System
K102927	Consensus Orthopedics Knee System
K131864	United Orthopedics CMA U2 Tibial Baseplate

D. DEVICE DESCRIPTION

Optimotion™ Blue Total Knee System consists of femoral, tibial tray, tibial insert, and patella resurfacing components, tibial stem extensions and a tibial plug. The tibial trays are composed of Ti-6Al-4V alloy, both non-porous (uncoated - cemented) or porous (cemented or cementless). All tibial insert and patella components are composed of UHMWPE with Vitamin E. The tibial stem extensions and plug are composed of Ti-6Al-4V alloy. The femoral components are composed of CoCrMo alloy either uncoated (non-porous - cemented), and coated with porous CoCrMo sintered porous coating. The non-porous cemented tibial tray and femur are only to be used with PMMA bone cement. The porous tibial tray can either be used with cement or cementless. The porous CoCr femur is compatible with both cemented and cementless applications. The Optimotion™ Blue Total Knee System is intended for cemented or uncemented replacement of the tibia, patella and femur articular surfaces of the knee.

Femoral Components: Femoral components are designed in right and left configurations and are available in cruciate retaining (CR) designs.

Tibial Insert: The tibial inserts are available in cruciate retaining asymmetric design (CR) and highly congruent (HCCR) design. Both Tibial Inserts options are available in a range of thicknesses.

Tibial Tray Components: Symmetric Tibial Trays Components are compatible with both types of Tibial Inserts.

Patellar Components: Patellar resurfacing components are available in only cemented symmetric options. Use of patellar component is optional.

Modular Stem Extensions: Modular stem extensions are available in a variety of stem lengths and diameters for use in cemented and non-cemented applications. Modular stem extensions are not intended for use when there is insufficient bone stock available for implantation.

Tibial Plug: The Tibial Plug is available in one universal size and mates with both Cemented and Porous Tibial Tray Components. The use of the Tibial Plug is optional.

E. INDICATIONS FOR USE

- Painful, disabling joint disease of the knee resulting from; noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configurations and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques.

Optimotion™ Blue Porous Tibial Baseplate components are indicated for Cemented or Cementless use. The Optimotion™ Blue Porous CR Femoral components are indicated for Cemented or Cementless use. The Optimotion™ Blue CEMENTED CR Femoral and CEMENTED Tibial Baseplate components are indicated for cemented use only.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Optimotion™ Blue Total Knee System is a total knee system comprised of prosthetic implants and reusable instruments. The implant geometry is optimized for total articular surface replacement of the femorotibial joint. The tibial tray consists of eight (8) sizes, the tibial insert is offered in seven (7) thicknesses, the femoral component is available in eight (8) sizes, and the patella implant is available in six (6) different sizes. The porous femoral and tibial components have porous surfaces for cemented and/or cementless fixation. The tibial baseplate possesses a locking mechanism to retain the tibial insert. The tibial-femoral articulation is semi-constrained.

G. PERFORMANCE DATA

Pre-clinical performance testing was performed for Optimotion™ Blue Total Knee System per the FDA Guidance Document "*Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA*", ASTM and ISO consensus standards, and publicly available information. The performance data presented in this 510(k) notification show Optimotion™ Blue Total Knee System to meet the standards for total knee replacement devices and to be substantially equivalent to the predicate device.

- Tibial baseplate fatigue strength per ASTM F1800. Tibial baseplate, tibial stem fatigue and fretting corrosion assessment.
- Range of Motion (ROM), contact pressure, and area of tibiofemoral articulation of UHMWPE inserts per ASTM F2083. Constraint testing / analysis per ASTM F1223.
- Resistance to dislodgement of the tibial insert per ASTM F1814.
- Assessment of wear of the 100 kGy cross-linked, vitamin E stabilized UHMWPE tibial inserts per ISO 14243-(1)-2002.
- Evaluation of the porous fixation surfaces for strength and morphology per the FDA guidance document "Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone Or Bone Cement", and relevant ASTM standards.
- Validation of additive manufacturing process for the tibial baseplate.
- Validation studies of packaging and shelf life.
- Bacterial Endotoxin Test (BET) per ANSI/AAMI demonstrating the subject device to meet the limit of ≤ 20 EUs per device.

H. CONCLUSION

Optimotion™ Blue Total Knee System is substantially equivalent to the identified predicate devices based on the indications for use, materials, design, size, and performance data presented in this 510(k) notification.