June 27, 2024

Optimotion Implants, LLC
Cassidy Larwood
Product Development Engineer
6052 Turkey Lake Road
Suite 170
Orlando, Florida 32819

Re: K240938
Trade/Device Name: The Optimotion™ Blue Plus Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OIY
Dated: April 5, 2024
Received: April 5, 2024

Dear Cassidy Larwood:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.06.27 13:52:32 -04'00'

For: Lixin Liu, 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)*
K240938

Device Name
The Optimotion™ Blue Plus 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.
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.
• Severe anteroposterior instability of the knee joint
• Optimotion™ Blue Plus Knee System and Optimotion™ Blue Total Knee System non-porous implant components are indicated for cemented use only.
• Optimotion™ Blue Plus Knee System and Optimotion™ Blue Total Knee System porous coated implant components are indicated for cemented or uncemented use.

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 Plus 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 Optimotion™ Blue Plus Knee System.

CONTACT DETAILS

Applicant Name:	Optimotion Implants LLC
Applicant Address:	6052 Turkey Lake Rd. Suite 170. Orlando, FL 32819, United States
Applicant Contact Telephone:	877-678-6686
Applicant Contact:	Cassidy Larwood

DEVICE NAME

Device Trade Name:	The Optimotion™ Blue Plus Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name:	Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis

Regulation Number:	21 CFR section 888.3565
Product Codes:	MBH, JWH, OIY

PREDICATE DEVICE

K141056	Stryker Triathlon Knee System; Product Code MBH, JWH

DEVICE DESCRIPTION SUMMARY

The Optimotion™ Blue Plus Knee System is a line addition to the Optimotion™ Blue Total Knee System (K191084) consisting of a posterior stabilizing (PS) femoral and PS tibial insert components. The femoral component is composed of CoCrMo alloy, non-porous for cemented use. The femoral component is to be used with PMMA bone cement. The tibial insert components are composed of UHMWPE with Vitamin E. The Optimotion™ Blue Plus Knee System is intended for cemented replacement of the femur and articulating surfaces of the knee.

Femoral Component: The femoral component is symmetric. The femoral component is available in posterior stabilizing (PS) design and is offered in eight (8) sizes. The system is designed to allow each size femoral component to be interchangeable with the next size up, the same size, or the next size down Optimotion™ Blue Tibial Tray and corresponding Optimotion™ Blue Plus PS Tibial Insert.

Tibial Inserts: The PS Tibial Insert components are symmetric and available in three configurations for varying levels of constraint. The three configurations from lowest to highest constraint are Low Post (LP), Low Post Plus (LP+), and High Post (HP). The LP Tibial Insert has the shortest and smallest perimeter post and the HP Tibial Insert has the highest and largest perimeter post, with the LP+ containing a post that is between the LP and HP post sizes. Each configuration of PS Tibial Insert is offered in eight (8) sizes and seven (7) thicknesses. The tibial insert components are compatible with the Tibial Tray Components of the Optimotion™ Blue Total Knee System.

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.
- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint
- Optimotion™ Blue Plus Knee System and Optimotion™ Blue Total Knee System non-porous implant components are indicated for cemented use only.
- Optimotion™ Blue Plus Knee System and Optimotion™ Blue Total Knee System porous-coated implant components are indicated for cemented or uncemented use.

INDICATIONS FOR USE COMPARISON

The device has the same indications for use compared to the predicate device.

TECHNOLOGICAL COMPARISON

The subject device is a line extension of the FDA cleared Optimotion Blue Total Knee System (K191084) using Stryker Triathlon PS Components (K141056) as a predicate device for the posterior stabilizing functionality. As such, the subject device has characteristics of both systems with no new technological characteristics. Namely, the material of the tibial inserts

and the locking mechanism of the tibial inserts to the tibial tray are the same in the subject device as the Optimotion Blue Total Knee System (UHMWPE with Vitamin E using a Dovetail locking mechanism). The articulating surface of the subject Optimotion Blue Plus PS Tibial Inserts are the same as the FDA cleared Optimotion Blue HCCR Tibial Inserts. The design of the tibial eminence (tibial post) of the LP and HP PS Tibial Inserts of the subject device are comparable in design to the Tibial Bearing Insert-PS and Total Stabilizer+ Tibial Inserts of the predicate device, respectively. Similarly, the design of the intercondylar box of the PS Femur of the subject device is comparable to that of the predicate device. The material and processes to manufacture the proposed PS Femoral Component (CoCrMo) is the same as in the FDA cleared Cemented CR Femoral Component of the Optimotion Blue Total Knee System. Further, the intended use and indications for use are the same in the subject device as the predicate device.

PERFORMANCE DATA

The performance data presented in this 510(k) notification show Optimotion™ Blue Plus Knee System to meet the standards for total knee replacement devices and to be substantially equivalent to the predicate device.

The articulating surface of the PS Femoral Component and PS Tibial Inserts are identical to the articulating surface of the CR Femoral Component and HCCR Tibial Inserts of the 510k approved Optimotion Blue Total Knee System (K191084). As such, the wear simulation analysis that was performed on those approved components per ISO 14243-(1)-2002 will be referenced for the subject device.

The minimum tibial insert thickness was tested using Solidworks CAD drawing analysis to confirm that the minimum thickness of the thinnest, smallest size PS Tibial Insert is greater than 6mm. Solidworks CAD analysis was also used to demonstrate the range of motion of the PS Femoral Component and PS Tibial inserts.

The locking mechanism of the PS Tibial Inserts are identical to the locking mechanisms of the CR and HCCR Tibial Inserts in the Optimotion Blue Total Knee System. However, due to the addition of a post on the PS Tibial Inserts, shear static and fatigue testing were performed using the thickest and largest size HP PS Tibial Insert.

Validation studies of packaging and shelf life and Bacterial Endotoxin Tests (BET) per ANSI/AAMI were performed on the already FDA cleared Optimotion Blue Total Knee System and are referenced in this 510(k) submission. The subject devices are packaged in the same manner and at the same facility as the cleared devices. The subject devices are comprised of the same material as the cleared devices.

CONCLUSION

Optimotion Blue Plus 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.