March 14, 2022

Optimotion Implants, LLC
Andy Rynearson
CEO
6052 Turkey Lake Road
Orlando, Florida 32819

Re: K220049
Trade/Device Name: Optimotion Implants Porous Metal-Backed Patella
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: January 4, 2022
Received: January 6, 2022

Dear Andy Rynearson:

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.
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)*
K220049

Device Name
Optimotion Implants Porous Metal-Backed Patella

Indications for Use *(Describe)*
The Optimotion Implants Porous Metal-Backed Patella is intended for cemented or cementless applications when resurfacing the surgically prepared patella as part of primary Total Knee Arthroplasty (TKR). The Optimotion Implants Metal-Backed Patella is compatible for use with components of the Optimotion™ Blue Total Knee System components (K191084).

General Total Knee Arthroplasty (TKR) Indications:

- 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 porous tibial tray and porous CR femoral components are indicated for cemented or cementless use.
- Optimotion cemented CR Femoral and cemented tibial tray 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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6. 510(k) Summary

The following 510(k) Summary is provided in accordance with 21 CFR 807.92.

6.1 510(k) Owner and Registration

Owner's Name:	Optimotion Implants, LLC.
Address:	6052 Turkey Lake Rd, Suite 170 Orlando, FL 32819
Phone Number:	(321) 316-2601
Fax Number:	N/A
Date Summary Prepared:	January 4, 2022
Establishment Registration Number:	N/A

6.2 510(k) Contact

Contact:	Andy Rynearson
Address:	6052 Turkey Lake Rd, Suite 170 Orlando, FL 32819
Phone Number:	(321) 316-2601
Fax Number:	N/A
Contact Person:	Andy Rynearson

6.3 Device Name and Classification

Device Trade Name:	Optimotion Implants Porous Metal-Backed Patella
Device Common Name:	Total Knee Joint Replacement
Regulation Number and Description:	21 CFR 888.3560, 21 CFR 888.3565
Device Class:	Class II
Product Codes:	MBH, JWH, OIY
Advisory Panel:	87 (Orthopedic)

6.4 Legally Marketed Predicate

Optimotion Implants is utilizing the Stryker Triathlon™ Tritanium™ Metal-Backed Patella (K132624) as the predicate device. The Optimotion Implants Porous Metal-Backed Patella features component designs, materials, indications, and manufacturing methods that are similar to the Stryker Triathlon™ Tritanium™ Metal-Backed Patella.

Premarket Notification:

Optimotion Implants Porous Metal-Backed Patella

6.5 Device Description

The Optimotion Implants Porous Metal-Backed Patella is an extension of The Optimotion™ Blue Total Knee System (K191084) product line for use in primary Total Knee arthroplasty. The Optimotion Porous Metal-Backed Patella will come in two variations Onset and Inset styles. It is a sterile, single use, non-modular porous metal-backed patella that is manufactured from UHMWPE (ASTM F648) and commercially pure titanium (ASTM F1580). The device is offered in a symmetric design that is available in multiple sizes. The metal backing features an additive manufactured porous posterior surface and three additive manufactured porous pegs to provide cemented or cementless fixation to bone.

6.6 Intended Use

The Optimotion Implants Porous Metal-Backed Patella is intended for cemented or cementless applications when resurfacing the surgically prepared patella as part of primary Total Knee Arthroplasty (TKR). The Optimotion Implants Metal-Backed Patella is compatible for use with components of the Optimotion™ Blue Total Knee System components (K191084).

General Total Knee Arthroplasty (TKR) Indications:

- 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 porous tibial tray and porous CR femoral components are indicated for cemented or cementless use.
- Optimotion cemented CR Femoral and cemented tibial tray components are indicated for cemented use only.

6.7 Summary of Technological Characteristics

Device comparisons and performance testing show that the Optimotion Implants Porous Metal-Backed Patella is substantially equivalent to its predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

6.8 Performance Testing

Optimotion Implants Porous Metal-Backed Patella utilizes the Performance testing of the Optimotion™ Blue Total Knee System (K191084) which was performed per the FDA "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA", consultations with professionals at testing centers, Optimotion™ Implants' surgeon advisors, and engineering consultants as follows. Optimotion Implants Porous Metal-Backed Patella utilizes the same additive manufacture and processes as the currently cleared Optimotion™ Blue Total Knee System (K191084). The completed testing can be found in Appendix E-1. The following is what was tested.

- Additive Titanium Porous Structure
    - Percent Porosity and Average Pore Size
    - Shear Static and Fatigue

Premarket Notification:

Optimotion Implants Porous Metal-Backed Patella

6.9 Conclusions

The subject device has similiar design features, materials, and indications for use as the predicate devices. The testing performed for the predicate device indicates that the Optimotion Implants Porous Metal-Backed Patella is safe for clinical use.

The Optimotion Implants Porous Metal Backed Patella is substantially equivalent to the predicate device.