May 17, 2022

Biocore9, LLC.
Stephen Peoples
Consultant
9 Whippany Rd, Bldg A1, Unit 12
Whippany, New Jersey 07981

Re: K212761
Trade/Device Name: Biocore9 Acetabular Cup System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: April 15, 2022
Received: April 15, 2022

Dear Stephen Peoples:

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,

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212761

Device Name
Biocore9 Acetabular Cup System

Indications for Use *(Describe)*

1. Painful hip arthritis refractory to medical management resulting from post-traumatic arthritis, osteoarthritis, or rheumatoid arthritis.
2. Painful femoral head. cup arthroplasty, or bi-polar or universal type femoral head replacement.
3. Cases where more conventional arthroplasty techniques or arthrodesis are contraindicated because of a difficult clinical management problem, age, sex, occupation, or height of the patient

The Biocore9 Acetabular Cup System components are intended for use in total hip arthroplasty in primary or revision surgery of skeletally mature patients. The Biocore9 Acetabular Cup System shells and liners are single use implants intended for cemented or cementless arthroplasty.

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.

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Biocore9 Acetabular Cup System.

Submitted by:	Biocore9, LLC. 9 Whippany Road, Bldg A1, Unit 12. Whippany NJ 07981 (973)-585-4281
Contact Person:	Stephen J. Peoples, VMD, MS, FAOA Email: speoplesVMD@gmail.com
Date Prepared:	August 30th, 2021
Proprietary Name: Common Name:	Biocore9 Acetabular Cup System Acetabular Cup System
Classification Name:	21 CFR 888.3358 –Hip Joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis 21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis
Device Product Codes:	LPH, JDI
Primary Predicate Device:	**K842202** Endomedics Inc. Acetabular Cup and screw
Additional Predicate Devices:	**K884888** Protek Inc. Modified New Jersey Acetabular component &bone screws
Reference Devices:	**K033273** DePuy Pinnacle Acetabular Cup System, ESL Marathon liners, Ultima Unipolar Femoral Heads, Self-Centering Hip Prosthesis. **K182468 & K151264** Stryker Modular Dual Mobility Acetabular System **K062148** Pinnacle AltrX Acetabular cup Liner DePuy: Marathon **K201219** Biocore9 Femoral Head Resurfacing Component **K193122** Biocore9 Humeral Resurfacing System

Device Description

The subject Biocore9 Acetabular Cup System includes acetabular shells, liners, and acetabular bone screws. Components are intended to replace the articular surface of the acetabular socket in the patient's hip joint. It is intended for the reconstruction of painful and/or severely disabled hip joints resulting from osteoarthritis or rheumatoid arthritis for patients who would be candidates for total hip procedure, whose acetabular socket has not been excessively damaged by disease or trauma and where damage is primarily associated with the articular surface damage. Acetabular components are available in nine sizes with available outside diameters from 50 mm to 66 mm in 2 mm increments. Bearing components are available in fourteen sizes from 39 mm to 52 mm ID in 1 mm increments. Screw components are available in 6.5 mm diameter in five sizes from 15 mm to 50 mm lengths.

Biocore9 Cancellous Bone screws are manufactured from Ti6Al4V alloy (ASTM F136) with low profile screw heads designed to fit the Acetabular shells with nominal diameter of 6.5 mm.

The acetabular shell components are manufactured from Ti-6Al-4V alloy (ASTM F136) with a single radius spherical outer geometry coated with three layers of Commercially Pure (CP)-Ti (ASTM F67) spherical bead porous coating allowing for cemented or cementless fixation and an anatomical shaped rim to limit impingement with the femoral side of the joint or the psoas muscle. A crescent peripheral groove provides for assembly interlock and three rim tabs provide anti rotational interlock with the bearing liner. The acetabular shells are available in two configurations: one with no screw holes and a second with five screw holes for supplemental bone screw fixation. All surfaces are coated with Titanium Nitride (TiN) thin film ceramic coating. Porous structured acetabular shells are intended for cementless or cemented fixation.

The acetabular cup bearing liner components are manufactured from UHMWPe (ASTM F648), GUR 1020 Highly cross linked UHMWPe (75KGy MRad /post irradiation annealed) which locks into the acetabular cup shell with ten flexible lip tabs and has three rotation resisting tabs. The liners have inner diameters (ID) intended for use with modular, unipolar, self-centering (bipolar), metallic or ceramic femoral heads within the 39-52 mm OD range and articulate with a femoral head of an appropriate corresponding diameter.

The components of the subject device are compatible with the BioPro PSL Hip System femoral head and stems.

The 510k numbers for the compatible BioPro devices are listed below:

- BioPro PC Femoral Hip Component (K882146),
- BioPro Hemi-Endo Modular Head (K895886),
- BioPro Ziralloy Modular Femoral Head (K912641 & K925682),
- BioPro PSL Total Hip Replacement System (K922500),
- BioPro Hemi-Endo Modular Ceramic Head (K954768),
- BioPro BiPolar Head (K100761)

Indications for Use

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The Biocore9 Acetabular Cup System components are intended for use in total hip arthroplasty in primary or revision surgery of skeletally mature patients. Biocore9 Acetabular Cup System Shells and Liners are single use implants intended for cemented or cementless arthroplasty.

Non-Clinical Performance Testing

Performance testing was conducted in-order-to provide support in establishing substantial equivalence of technological characteristics.

- Testing was conducted for the Porous coating: Tensile strength (ASTM F1147), Shear strength (ASTM F1044), Porosity.
- Bearing Liner connection was tested for the worst case. Tests performed were push-out force, lever out force and axial torque (ASTM F1820).
- A range of motion analysis by 3D modeling (ISO 21535) was conducted for the typical worst-case evaluation and compared the subject system to the competitive devices in three planes.
- Bone screw testing was conducted in accordance with ASTM F543, Standard Specification and Test Methods for Metallic Medical Bone Screws, for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Wear simulation was conducted on the 52 mm ID highly cross-linked poly bearing liners. Prior to testing these were subjected to two EO-sterilization cycles and double duration accelerated aging. The wear simulation was in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1.
- Wear particle characterization was conducted (ASTM F1877).
- Testing was conducted for the TiN Coating: Thickness, Adhesion Strength to Ti6Al4V substrate, Abrasion resistance, Wear resistance Mode 1
- Dimensional and geometric comparison with predicate device was conducted.
- Jump Distance Analysis was conducted.
- Impingement fatigue testing per ASTM F2582 was conducted followed by post-impingement disassembly testing per ASTM F1820.

Summary of Technological Characteristics

Device comparisons and performance testing show that the Biocore9 Acetabular Cup System is substantially equivalent to the predicates in terms of intended use, indications for use, design, sizes, materials, performance characteristics, biocompatibility, sterilization, and operational principles.

Substantial Equivalence

The Biocore9 Acetabular Cup System shares the same indications for use as the predicate components and has comparable design features and technological characteristics. The fit and function of the subject device, supported by performance testing, does not raise any new questions of safety and effectiveness when compared to the predicate devices.