BioCore9 LLC
Steve Peoples
Consultant
9 Whippany Road, BLDG A1, Unit 12 A
Whippany, New Jersey 07981

January 19, 2021

Re: K201219
Trade/Device Name: Biocore9 Femoral Head Resurfacing Component
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Resurfacing Prosthesis
Regulatory Class: Class II
Product Code: KXA
Dated: December 21, 2020
Received: December 22, 2020

Dear Steve 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,

Vesa Vuniqi
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)*
K201219

Device Name
Biocore9 Femoral Resurfacing Head Component

Indications for Use *(Describe)*

The Biocore9 Femoral Resurfacing Head Component, used with cement, is indicated for the treatment of painful hip arthritis due to post-traumatic arthritis, osteoarthritis, or rheumatoid arthritis, as well as painful hip arthroplasty when sufficient femoral head and neck stock exist to stabilize a resurfacing femoral head. The Biocore9 Femoral Resurfacing Head Component is intended for cemented use only. This device is intended for hemi-arthroplasty 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Biocore9, LLC.
Femoral Resurfacing Head Component
Traditional 510(k)

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 Femoral Resurfacing Head Component.

Submitted by:	Biocore9, LLC. 9 Whippany Road, Bldg A1, Unit 12. Whippany NJ 0798 (973)-585-4281
Contact Person:	Stephen J. Peoples Email: speoplesVMD@gmail.com
Proprietary Name:	Biocore9 Femoral Resurfacing Head Component
Common Name:	Femoral Resurfacing Head
Classification Name and Reference:	21 CFR 888.3400, Class II Hip joint femoral (hemi-hip) metallic resurfacing prosthesis
Device Product Code, Device Panel:	KXA
Predicate Device:	Endotec Inc. Modified New Jersey Femoral Hip Resurfacing Component 510(k) #K904870

Device Description

The Biocore9 Femoral Resurfacing Head component is a non-constrained orthopedic implant intended to replace the articular surface of the existing femoral head in the patient's hip joint. The Biocore9 Femoral Resurfacing Head Component is intended for in the reconstruction of painful and/or severely disabled hip joints resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, or previously failed prosthesis. Sufficient bone stock on the femoral head and neck is necessary to stabilize a resurfacing femoral component. This device is intended for cemented use only. Components are available in thirteen sizes with available outside diameters 39.5, 41 ,42.5, 44, 45.5, 47, 49, 51, and 52.5 mm.

The Biocore9 Femoral Resurfacing Head Component is manufactured from Ti-6Al-4V alloy (ASTM F136-13) with a Titanium Nitride (TiN) thin film ceramic coating. The titanium nitride coating is an inert, highly adherent, near diamond-hard surface coating.

The Femoral Resurfacing component is axisymmetric with a truncated spherical shell and a tapered central alignment stem. The component consists of a thin-walled spherical shell. The internal surface of the spherical shell is covered with a porous coating consisting of titanium beads. The stem is not porous coated.

Indications for Use

The Biocore9 Femoral Resurfacing Head Component, used with cement, is indicated for the treatment of painful hip arthritis due to post-traumatic arthritis, osteoarthritis, or rheumatoid arthritis, as well as painful hip arthroplasty when sufficient femoral head and neck stock exist to stabilize a resurfacing femoral head. The Biocore9 Femoral Resurfacing Head Component is intended for cemented use only. This device is intended for hemi-arthroplasty only.

Substantial Equivalence

Biocore9 Femoral Resurfacing Head Component is substantially equivalent to the Endotec – Modified New Jersey Femoral Hip Resurfacing Component - K904870, since there are no significant differences in materials, form, fit, or functionality. See Table 1 for reference:

Performance Testing

Performance testing was conducted to provide support for establishing substantial equivalence. This testing included the following:

- TiN coating characterization; adhesion testing, thickness, hardness, scratch testing
- CP Ti porous coating characterization; Tensile strength, shear strength, porosity
- Mode 1 wear testing
- Abrasion resistance testing
- ISO 1143 Rotating beam fatigue testing

Table 1: *Device Comparison Summary.*

Device	Predicate: Endotec – Modified New Jersey Femoral Hip Resurfacing Component - K904870	Biocore9 Femoral Resurfacing Head Component
Design	Component is Axisymmetric with a truncated spherical shell with central tapered stem and porous coated inner surface. Available in several sizes.	Component is Axisymmetric with a truncated spherical shell with central tapered stem and porous coated inner surface. Available in several sizes.
Materials	Titanium alloy (ASTM F-136) with Ultracoat TiN Ceramic coating, Biocoat® porous coating on the non-articulating, inner surface.	Titanium alloy (ASTM F-136) with TiN Ceramic coating, components are porous coated on the non-articulating, inner surface.
Indications	The Endotec Modified New Jersey Femoral Hip Resurfacing Component is intended to treat painful hip arthritis due to post-traumatic arthritis, osteoarthritis, or rheumatoid arthritis, as well as hip cup arthroplasty when sufficient femoral head and neck stock exist to stabilize a resurfacing femoral head.	The Biocore9 Femoral Resurfacing Head Component, used with cement, is indicated for the treatment of painful hip arthritis due to post-traumatic arthritis, osteoarthritis, or rheumatoid arthritis, as well as painful hip arthroplasty when sufficient femoral head and neck stock exist to stabilize a resurfacing femoral head. The Biocore9 Femoral Resurfacing Head Component is intended for cemented use only. This device is intended for hemi-arthroplasty only.
Size availability	36.5, 38, 39.5, 41 ,42.5, 44, 45.5, 47, 49, 51, 52.5 (mm)	39.5, 41 ,42.5, 44, 45.5, 47, 49, 51, 52.5 (mm)
Anatomical Site	Femoral Head	Femoral Head
Sterilization	Gamma Irradiation	Gamma Irradiation
510(K) Number	K904870	K201219