May 15, 2020

Biocore9, LLC.
Stephen J. Peoples
Official Correspondent
9 Whippany Road, Bldg A1, Unit 12
Whippany, New Jersey 07981

Re: K193122
Trade/Device Name: Biocore9 Humeral Resurfacing System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: November 12, 2019
Received: November 12, 2019

Dear Stephen J. 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,

For: Michael Owens
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)*
K193122

Device Name
Biocore9 Humeral Resurfacing System

Indications for Use *(Describe)*
The Biocore9 Humeral Head Resurfacing Shoulder Component is intended for the reconstruction of painful and/or severely disabled shoulder joints resulting from osteoarthritis and rheumatoid arthritis. For proper function of this device, the humeral head and neck must be of sufficient bone stock to support the loads on it. Also, the presence of an intact or reconstructable rotator cuff is important for proper functioning and dislocation resistance. Porous-coated components are intended for cemented use only. This device is indicated 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.

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Biocore9, LLC.
Humeral Resurfacing Shoulder System
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 Humeral Resurfacing Shoulder.

Submitted by:	Biocore9, LLC. 9 Whippany Road, Bldg A1, Unit 12. Whippany NJ 07981
Contact Person:	Stephen J. Peoples, VMD, MS, FAOA Email: speoplesVMD@gmail.com
Proprietary Name:	Biocore9 Humeral Resurfacing Shoulder
Common Name:	Humeral Resurfacing Head
Classification Name and Reference:	21 CFR 888.3690, Class II
Device Product Code, Device Panel:	HSD
Predicate Device:	Buechel-Pappas, Humeral Head Resurfacing Component 510(k) #K992394

Device Description

The Biocore9 Humeral Head Resurfacing component is a non-constrained orthopedic implant intended to replace the articular surface of the existing humeral head in the patient's shoulder joint. It is intended for the reconstruction of painful and or severely disabled shoulder joints resulting from osteoarthritis or rheumatoid arthritis for patients who would be candidates for total shoulder or hemi shoulder procedure, whose proximal humerus has not been excessively damaged by disease or trauma and where damage is primarily associated with the articular surface of the humeral head. It is primarily intended to articulate with intact, natural, glenoid. Components are available in five sizes with available outside diameters from 40 mm to 56 mm in 4 mm increments.

The Biocore9 Humeral Resurfacing Head Component is manufactured from Ti-6Al-4V alloy (ASTM F136-13) with a Titanium Nitride (TiN) thin film ceramic coating. The Humeral Resurfacing component is axisymmetric with a truncated spherical shell and a tapered central stem. The component consists of a thin walled spherical shell. The Humeral resurfacing Component's rim is anatomical with a rounded relief. The exterior of the spherical surface is intended to articulate with the Glenoid.

The internal surface of the spherical shell is covered with a porous coating consisting of titanium beads. The stem is not porous coated.

Intended Use

The Biocore9 Humeral Head Resurfacing Shoulder Component is intended for the reconstruction of painful and/or severely disabled shoulder joints resulting from osteoarthritis and rheumatoid arthritis. For proper function of this device, the humeral head and neck must be of sufficient bone stock to support the loads on it. Also, the presence of an intact or reconstructable rotator cuff is important for proper functioning and dislocation resistance. Porous-coated components are intended for cemented use only. This device is indicated for hemi-arthroplasty only.

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, Shear strength, Porosity
Testing was conducted for the TiN Coating: Thickness, Adhesion Strength to Ti6Al4V substrate, Abrasion resistance, Wear resistance Mode 1

Substantial Equivalence

Biocore9 Humeral Resurfacing Shoulder System is substantially equivalent to the Endotec – Buechel-Pappas Humeral Resurfacing Component - K992394, since there are no significant differences in form, fit, or functionality.