December 22, 2023

Serf
℅ Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre Dame de Llle Perrot, Quebec J7W 3J6
Canada

Re: K223745
Trade/Device Name: Novae® Dual Mobility System, Hype® Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: November 30, 2023
Received: November 30, 2023

Dear Robert Poggie:

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,

Christopher Ferreira -S

for

Limin Sun, 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)*
K223745

Device Name
Novae® Dual Mobility System
Hype® Hip System

Indications for Use *(Describe)*

The Novae® Dual Mobility and Hype® Hip Systems are indicated for total hip replacement, which includes:
• Osteoarthritis,
• Femoral neck fracture,
• Dislocation risk,
• Osteonecrosis of the femoral head,
• Revision procedures where other treatments or devices have failed and if bone reconstruction so permits.

Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular cup is indicated for cemented use.

Hype® SCS, SCC, SCL, SCV, SCC mini, and SCLA mini hip stems are intended for press-fit 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.

510(k) SUMMARY for K223745

In accordance with 21 CFR 807.92, the following information is a 510(k) summary for the Novae® Dual Mobility System and Hype® Hip System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, NDIP, Québec, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone & Fax Number:	514-901-0796
Date of Submission:	December 22, 2023

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Serf
Manufacturer Address:	85 avenue des Bruyères, 69150 Décines-Charpieu – France
Registration Number:	3008668801
Contact Name:	Jean-Charles MONCENIS
Title:	Regulatory and Clinical Affairs Manager
Device Trade Names:	Novae® Dual Mobility System Hype® Hip System
Device Common Name:	Hip replacement prosthesis
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Classification Code:	LZO, MEH
Classification Panel:	Orthopedic
Regulation Number:	Primary regulation: 21 C.F.R. § 888.3353

C1. PRIMARY PREDICATE DEVICE

K181744	Serf BI-MENTUM™ dual mobility system

C2. PREDICATE DEVICES

K111572	Serf NOVAE® dual mobility acetabular cup
K190344, K123991, K042992	DePuy Corail Hip Prosthesis
K082239, K042959	DePuy C-Stem AMT
K160907, K150862	DePuy Actis Hip Prosthesis
K980513, K011533	DePuy CoCrMo and Ceramic femoral heads

D. DEVICE DESCRIPTION

The Novae® Dual Mobility System consists of cementless and cemented acetabular shells and a polyethylene liner. Novae® XPEO-E liners are made from highly crosslinked vitamin E stabilized polyethylene and are spherical in geometry for dual mobility articulation. The inner articular surface mates and retains a Biolox® delta ceramic or CoCrMo metal femoral head. The outer articular surface articulates within the highly polished inner diameter of Novae® cementless or cemented cups. Novae® cups are manufactured from stainless steel, with press-fit options coated with titanium and hydroxyapatite (HA). Pegs and cortical bone screws for optional ancillary fixation are made from stainless steel.

Hype® press-fit hip stems are compatible with the Novae® Dual Mobility System and Serf CoCrMo and Biolox® delta femoral heads. Hype® press-fit hip stems are made from titanium alloy coated with titanium and HA.

The primary purpose of this 510(k) notification is a line extensions to the 510(k) cleared Novae® acetabular cups (K111572) that are compatible with: (1) liner option made from highly crosslinked and vitamin E stabilized polyethylene (XPEO-E), (2) femoral heads made from CoCrMo alloy and Biolox® delta ceramic, and (3) Hype® press-fit hip stems.

E. INDICATIONS FOR USE

The Novae® Dual Mobility and Hype® Hip Systems are indicated for total hip replacement, which includes:

- Osteoarthritis,
- Femoral neck fracture,
- Dislocation risk,
- Osteonecrosis of the femoral head,
- Revision procedures where other treatments or devices have failed and if bone reconstruction so permits.

Sunfit TH, Novae® E TH, and Coptos TH acetabular cups are intended for press-fit use and Novae® Stick acetabular cup is indicated for cemented use.

Hype® SCS, SCC, SCL, SCV, SCC mini, and SCLA mini hip stems are intended for press-fit use.

F. TECHNOLOGICAL CHARACTERISTICS AND COMPARSION

The Novae® Dual Mobility System has the same intended use and similar indications for use as the primary predicate device, the Bi-Mentum™ Dual Mobility Acetabular Cup (K181744). The design and materials for Novae® acetabular cups, pegs, and bone screws are the same as those for the primary predicate device. The design of the XPEO-E polyethylene liner is the same

as the primary predicate, with the material for the subject device being made from highly crosslinked and vitamin E stabilized UHMWPE that is more resistant to wear and oxidation than conventional polyethylene. The CoCrMo and ceramic femoral heads are the same material, size, and design as previous compatible heads with the Bi-Mentum™ Dual Mobility System. Hype® cementless hip stems are made from the same materials and similar sizing and design principles as the predicate hip stem devices.

G. PERFORMANCE DATA AND SUBSTANTIAL EQUIVALENCE

Laboratory testing and engineering analyses were conducted to verify that the performance characteristics of the Novae® Dual Mobility and Hype® Hip System are sufficient for the intended use and to establish substantial equivalence. The following bench tests and analyses were performed and met predetermined acceptance criteria where specified:

- Range of motion analysis for Hype® hip stems and Novae acetabular cups (ISO 21535)
- Head-liner assembly / disassembly tests
- Lever-out testing for Novae® acetabular cups and liners (ASTM F1820-13)
- Impingement analyses and testing for Hype® hip stems and Novae® acetabular cups (ASTM F2582)
- Articular surface wear for pristine, outer bearing only, and abrasive conditions (ISO 14242-1)
- Fatigue strength testing of Hype hip stems (ISO 7206-4, -6)
- Fretting corrosion of Hype hip stem tapers and CoCrMo femoral heads (ASTM F1875)
- Torque-off and pull-off testing of femoral heads and Hype® hip tapers (ISO 7206-10, -13)
- Fatigue, post-fatigue burst strength of femoral head from stem (ISO 7206-10 and ASTM F2345-21)
- Physical, chemical, and mechanical tests and analyses of titanium and HA coatings for cementless Hype Hip Stems (ASTM F1854-15, F1160-14, F1044-05, F1147-05, F1978-18, F1185-03, F1926-14, F2024-10, F1609, ISO 13779-3, -6)
- Assessment of MRI compatibility and determination of conditional labeling requirements per ASTM F2503 and performance testing per ASTM F2052, F2213, F2182A, and F2119
- Assessment of biocompatibility of Novae® Dual Mobility and Hype® devices per ISO 10993-1
- Bacterial Endotoxin Testing (BET) / LAL chromogenic method demonstrating acceptable levels of endotoxins

The Novae® Dual Mobility and Hype® Hip Systems have the same intended use, similar indications for use, the same or similar materials and design features to the predicate devices. The results of performance testing and engineering analyses support substantial equivalence.

H. CONCLUSIONS

Comparison of the Novae® Dual Mobility System and Hype® Hip System components with the predicate devices demonstrate substantial equivalence of intended and indicated use, technological characteristics, materials, and principles of operation. The performance data demonstrate safety and equivalence of the subject and predicate.