Serf
% Catherine Gloster
Founder and Principal Consultant
Gloster Biomedical International
577 N Hope Avenue
Santa Barbara, California 93110

December 11, 2018

Re: K181744
Trade/Device Name: BI-MENTUM™ dual mobility 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: October 17, 2018
Received: October 22, 2018

Dear Catherine Gloster:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.12.11 12:15:09 -05'00'

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181744

Device Name
BI-MENTUM™ Dual Mobility System

Indications for Use *(Describe)*
BI-MENTUM™ Dual Mobility System is 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

BI-MENTUM™ PressFit Cup, BI-MENTUM™ Plus Cup and BI-MENTUM™ Revision Cup are intended for press-fit use and BI-MENTUM™ Cemented Cup is indicated for cemented 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date: June 27th, 2018

Company name and address: SERF
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FRANCE
Phone: +33 4 72 05 60 10
Fax: +33 4 72 02 19 18

Contact person: Jean-Luc AURELLE
General Manager

Date prepared: June 27th, 2018

Trade name: BI-MENTUM™ dual mobility system

Common name: Total hip prosthesis - Acetabular component

Classification name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353, Product Code LZO/MEH)

Device description

The BI-MENTUM™ dual mobility system is composed of a metallic shell fixed in the acetabulum and a polyethylene liner.

Cemented metallic shell

- BI-MENTUM™ Cemented Cup: the cemented metallic shell is made of stainless steel according to ISO 5832- 1. The outer surface is sandblasted and presents macro-volumes to augment contact between the implant and the cement. The inner surface is highly polished.

Cementless metallic shell

The cementless metallic shell is made of stainless steel according to ISO 5832-1 and is coated with a CP titanium and hydroxyapatite plasma spray (double layer coating) on the outer surface and is highly polished on the inner surface.

Three cementless metal-backs are available:

- BI-MENTUM™ PressFit Cup: this version is available without the pegs and screw, and is a press fit only.
- BI-MENTUM™ Plus Cup: it has 3 fixation points (2 divergent pegs towards the pubis and ischium and 1 cortical screw through a flange towards the ilium).
- BI-MENTUM™ Revision Cup: it has 5 fixation points (2 divergent pegs towards the pubis and ischium, cortical screws through 2 flanges towards the ilium and 1 foramen hook).

Liner
The liner is made of Ultra-High-Molecular-Weight Polyethylene according to ISO 5834-2. The liner is mobile (free) in the metallic shell and retained on the prosthetic femoral head. Liners can be used with Ø22,2 or 28 mm prosthetic femoral heads.

Pegs and cortical screws
When applicable, primary fixation can be reinforced by impacted pegs and self-tapping cortical screws made of stainless steel according to ISO 5832-1.

Substantial equivalence claimed to predicate devices
BI-MENTUM™ dual mobility system is the same product as NOVAE® Dual Mobility Acetabular Cup cleared in 2011 (K111572, SERF).
There is no change in the design of the acetabular cup, no change in the fundamental scientific technology of the device. Newly validated cup/head + stem assembly are substantially equivalent to the NOVAE® Dual Mobility Acetabular Cup yet validated assembly (K111572, SERF) in terms of mechanical safety and performances.

Device	**BI-MENTUM™ dual mobility system**	**NOVAE® Dual Mobility Acetabular Cup**
510(k) number	/	K111572
Intended use		
Total hip replacement	Yes	Yes
Cemented/Cementless	Yes/Yes	Yes/Yes
Primary/Revision	Yes/Yes	Yes/Yes
Design		
Dual mobility	Yes	Yes
Metal-back and a mobile liner	Yes	Yes
Screws	Cortical	Cortical
Pegs	Grooved	Grooved
Liner is retained on the head	Yes	Yes
Materials		
Metal-back	Stainless steel (ISO 5832-1)	Stainless steel (ISO 5832-1)
Metal-back coating	Commercially pure titanium and hydroxyapatite	Commercially pure titanium and hydroxyapatite
Liner	Liner: UHMWPE (ISO 5834-2)	Liner: UHMWPE (ISO 5834-2)
Screws and Pegs	Stainless steel (ISO 5832-1)	Stainless steel (ISO 5832-1)

Intended use
BI-MENTUM™ dual mobility system is 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

BI-MENTUM™ PressFit Cup, BI-MENTUM™ Plus Cup and BI-MENTUM™ Revision Cup are intended for press-fit use and BI-MENTUM™ Cemented Cup is indicated for cemented use.

Non-clinical Test Summary

BI-MENTUM™ dual mobility system is the same product as NOVAE® Dual Mobility Acetabular Cup cleared in 2011 (K111572, SERF). There is no change in the design of the acetabular cup, no change in the fundamental scientific technology of the device. However new cup/head + stem assembly were validated.

The following tests were conducted:

- Head insertion on force and Head Pull-Out testing (acceptance criteria was met)
- Range of motion analysis (acceptance criteria was met)
- Wear Analysis (acceptance criteria was met)

Clinical Test Summary

No clinical studies were performed

Conclusions Nonclinical and Clinical

BI-MENTUM™ dual mobility system is substantially equivalent to the predicate devices in terms of indications for use, design, material, function and performances.