LimaCorporate S.p.A
% David Mcgurl
Vice President, Regulatory Affairs-Orthopedics
Mcra, LLC.
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20001

March 17, 2023

Re: K221758
Trade/Device Name: SMR Stemless Anatomic
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: February 14, 2023
Received: February 14, 2023

Dear David Mcgurl:

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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2023.03.17 16:42:55 -04'00'

For Jiping Chen, MD, PhD, MPH
Division 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)*
K221758

Device Name
SMR Stemless Anatomic

Indications for Use *(Describe)*
The SMR Stemless Anatomic is indicated for total primary or revision shoulder joint replacement in patients suffering from disability due to:
• non-inflammatory degenerative joint disease including osteoarthritis;
• revision of previous surgeries of the shoulder that do not compromise the fixation (such as a failed SMR resurfacing implant);
• glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR TT Hybrid Glenoid only).

The SMR Stemless Anatomic is intended for uncemented 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

Device Trade Name: SMR Stemless Anatomic

Manufacturer:
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Udine, Italy

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Date Prepared: March 15, 2023

Classification: 21 CFR 888.3660

Class: II

Product Codes: PKC

Primary Predicate Device: Arthrex Eclipse Shoulder Prosthesis Anatomic (K183194)

Reference Devices:
LimaCorporate S.p.A. SMR Shoulder System (K100858, K110598, K110847, K113254, K133349, K143256, K153722, K163397, K161476)
Tornier, Inc. Simpliciti Shoulder System (K143552)
Zimmer GmbH Sidus Stem-Free Shoulder (K171858)
Exactech Inc. Exactech Equinoxe Stemless Shoulder (K173388)
LimaCorporate S.p.A. PRIMA Humeral System (K212800)

Indications for Use:
The SMR Stemless Anatomic is indicated for total primary or revision shoulder joint replacement in patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis;
- Revision of previous surgeries of the shoulder that do not compromise the fixation (such as a failed SMR resurfacing implant);
- Glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR TT Hybrid Glenoid only).

The SMR Stemless Anatomic is intended for uncemented use.

Device Description:
The SMR Stemless Anatomic is a modular system comprised of a stemless core and humeral head adaptor taper. The modular components are available in various sizes and are interchangeable allowing for independent sizing and positioning. The SMR humeral heads were previously cleared (K161476, K100858), and the SMR Stemless Anatomic is compatible with the previously cleared Cemented SMR metal back Glenoid Components (K113254, K133349, K143256), Cemented SMR all polyethylene glenoid components (K100858, K130642, K153722), and SMR TT Hybrid Glenoid System (K163397).

Performance Testing:
The following testing was performed in support of the SMR Stemless Anatomic performance:

- Fatigue and Post Fatigue Pull-Out Testing
- Micromotion Testing
- Adaptor from Core Pull-Out Testing
- Head from Adaptor Pull-Out Testing
- Adaptor from Core Torque-Out Testing
- Head from Adaptor Torque-Out Testing
- Range of Motion
- Clinical Data

Clinical Data Summary:
Clinical data was provided from an EU post market study on 62 subjects who received the SMR Stemless Anatomic. The Arthrex Eclipse control data came from a published clinical study. The composite clinical success for SMR Stemless Anatomic is 89.9% (95% 1-sided lower bound confidence interval 83.2%) compared with the 92.3% (95% 1-sided lower bound confidence interval 82.3%) for the Arthrex Eclipse control group.

Additional supplemental data was provided, by obtaining patient level information from two published studies for the subject SMR stemless anatomic. The supplemental data was used to demonstrate adequate fixation of the stemless core at 24 month follow-up. Additionally, the composite clinical success was able to be calculated for one of the supplemental datasets (n=52). This composite clinical success for the SMR Stemless Anatomic was determined to be 96.2% (95% 1-sided lower bound confidence interval 91.1%).

Substantial Equivalence:
The SMR Stemless Anatomic is substantially equivalent in materials, indications, function and/or performance to the predicate device: Arthrex Eclipse Shoulder Prosthesis System (K183194).