Ignite Orthopedics LLC
Russ Parott
VP of Research and Development
700 Park Avenue Suite F
Winona Lake, Indiana 46590

July 16, 2021

Re: K203108
Trade/Device Name: Ignite Stemless Anatomic Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC, PAO
Dated: June 14, 2021
Received: June 15, 2021

Dear Russ Parott:

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,

Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

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)*
K203108

Device Name
Ignite Stemless Anatomic Shoulder System

Indications for Use *(Describe)*
The Ignite Stemless Anatomic Shoulder Prosthesis is intended for use in total shoulder replacement procedures to address the following:
• Osteoarthritis;
• Posttraumatic arthrosis;
• Focal avascular necrosis of the humeral head;
• Previous surgeries of the shoulder that do not compromise the fixation.

Fixation Methods
The stemless anchor is intended for cementless use. The glenoid is intended for cemented use 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.

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510(k) Summary

Prepared: June 15, 2021

Submitter:
Ignite Orthopedics LLC
700 Park Ave.
Suite F
Winona Lake, IN 46590

Contact:
Russ Parrott
VP of Research and Development
Phone: 574.527.2864
russ.parrott@igniteorthopedics.com

Proprietary Name: Ignite Stemless Anatomic Shoulder System

Common Name: Shoulder Arthroplasty System

Classification: Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-Constrained (21 CER §888.3660); Class II

Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer + Additive, Cemented (21 CER §888.3660); Class II

Product Codes: PKC, PAO

Predicate Devices:
K171858 (Primary), Sidus Stem-Free Shoulder, Zimmer GmbH

K202716, Ignite Anatomic Shoulder System, Ignite Orthopedics LLC

K143552, Simpliciti Shoulder System, Tornier, Inc.

K182516, Comprehensive Nano Stemless Shoulder, Biomet Manufacturing Corp

K183194, Arthrex Eclipse Shoulder Prosthesis System

K173388, Exactech Equinoxe Stemless Shoulder, Exactech Inc

K193226, AltiVate Anatomic Canal-Sparing (CS) Shoulder, Encore Medical, L.P

K083439, Synthes Epoca Shoulder Prosthesis System, Synthes (USA)

Device Description:
The Ignite Stemless Anatomic Shoulder System is total shoulder arthroplasty system consisting of stemless humeral implants (multiple sizes), offset taper adapter, humeral heads (38 - 57mm diameters), and glenoid components (multiple sizes).

The anatomic stemless humeral construct consists of an additively manufactured Ti-6Al-4V Stemless Humeral Implant, a wrought Cobalt-Chromium Humeral Head, and a wrought Ti-6Al-4V Taper Adapter. The all-poly Anatomic Glenoid consists of a Highly Crosslinked Alpha-Tocopherol (Vitamin-E) infused Ultra-High-Molecular-Weight-Polyethylene articulation surface. This device also has a 316L stainless steel pin pressed into it as an x-ray marker.

The system is provided with a set of instruments designed for preparation of the implant site and insertion of the implants into bone.

Intended Use / Indications:
The Ignite Stemless Anatomic Shoulder Prosthesis is intended for use in total shoulder replacement procedures to address the following:

- Osteoarthritis;
- Posttraumatic arthrosis;
- Focal avascular necrosis of the humeral head;
- Previous surgeries of the shoulder that do not compromise the fixation.

Fixation Methods
The stemless anchor is intended for cementless use. The glenoid is intended for cemented use only.

Summary of Technologies/Substantial Equivalence:
The Ignite Stemless Anatomic Shoulder System is substantially equivalent to the predicate devices in terms to of its intended use and indications, material, design, and sizes. While there are minor differences, the non-clinical testing described in the next section demonstrated safety and effectiveness and substantial equivalence between the subject and predicate devices.

Non-Clinical Testing:
The Ignite Stemless Anatomic Shoulder System underwent non-clinical testing and analyses to support a determination of substantial equivalence. The following were completed:

Predicate Comparison Evaluation
A detailed comparison of key technologies and feature dimensions was made between the subject device and predicate devices. The comparison concluded the subject device key technologies and feature dimensions are substantially equivalent to that of the predicate devices.

Humeral Anchor Loosening (Implant-To-Bone) – Static Stability

The Ignite Shoulder System Stemless Anchor static stability was evaluated via resistance to axial pull-out, torque-out, and lever-out. The subject devices were found to be substantially equivalent to legally marketed predicate devices, which were tested using the same test method and test equipment. The Ignite Stemless Anchors also exceeded clinically relevant loading conditions with the application of an adequate safety factor and the respective acceptance criteria were met.

Humeral Anchor Loosening (Implant-To-Bone) – Cyclic Loosening Evaluation

The Ignite Shoulder System Stemless Anchor was evaluated for resistance to cyclic loosening. The subject devices were found to be substantially equivalent to legally marketed predicate devices, which were tested using the same test method and test equipment. The Ignite Stemless Anchors also exceeded clinically relevant loosening displacement requirements and the respective acceptance criteria were met.

Range of Motion (RoM) Evaluation

An evaluation was conducted to ensure the RoM of the worst-case subject device components meet established specifications per ASTM F1378. The RoM targets were met.

Biocompatibility Assessments

The contact classification for the subject devices is Implant, Bone/Tissue with permanent contact (>30 days). A Biocompatibility Assessments was completed and provided per ISO 10993-1 and FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The devices were found to be biocompatible.

Porous Structure Characterization

The porous structure used for the subject device was fully characterized. The following data were provided:

- Shear Strength per ASTM F1044
- Tensile Strength per ASTM F1147
- Shear Fatigue per ASTM F1160
- Abrasion Resistance per ASTM F1978
- Stereological Evaluation per ASTM F1854

Construct Fatigue Testing

Fatigue testing was performed on the worst case shoulder construct with anatomically relevant loading to demonstrate that the strength of the device exceeds that required for the intended use. The acceptance criteria were met.

Taper Disassembly Evaluation

A mechanical evaluation was conducted to study the dissociation of production equivalent tapers used on the humeral side of the subject device. Testing was conducted per ASTM F2009. The acceptance criteria were met.

Shelf Life Evaluation

A shelf life evaluation per ISO 11607-1 and ISO 11607-2 was completed on the packaging materials that make up the sterile barrier. A five year shelf life was established based on the resultant data.

Sterilization Validation

Sterilization validation was completed using the VDmax method specified in ISO 11137-1 and ISO 11137-2. The Sterility Assurance Level (SAL) was found to be 10^{-6}.

Compatible Device Testing

The compatible devices that make up the total shoulder construct were tested, and the information provided in predicate device K202716. For the compatible glenoid, tests included polyethylene characterization, wear testing, loosening testing, torsional testing, and axial pullout testing.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Ignite Stemless Anatomic Shoulder System to the predicate device.

Conclusion:

A comparison of the subject and predicate devices, including comparison of the intended use, technological characteristics, and non-clinical testing results has demonstrated that the subject devices have a safety and effectiveness profile equivalent to that of the predicate devices. Thus, the subject devices are substantially equivalent to the predicate devices.