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

May 20, 2021

Re: K202716
Trade/Device Name: Ignite Anatomic Shoulder System
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS, PAO, HSD
Dated: April 19, 2021
Received: April 20, 2021

Dear Russ Parrott:

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
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)*
K202716

Device Name
Ignite Anatomic Shoulder System

Indications for Use *(Describe)*
The Ignite Anatomic Shoulder System is intended for use in total or hemi-shoulder replacement procedures to address the following:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Revision where other devices or treatments have failed.
- Correction of functional deformity.
- Fracture of the humeral head
- Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Fixation Methods
The humeral stem is intended for cemented or 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.

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510(k) Summary

Prepared: May 19, 2021

Submitter: Ignite Orthopedics LLC
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Suite F
Winona Lake, IN 46590

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

Proprietary Name of Subject Device: Ignite Anatomic Shoulder System

Common Name: Shoulder Arthroplasty System

Classification: Shoulder Joint, Metal/Polymer/Metal, Non-Constrained or Semi-Constrained, Porous Coated, Uncemented Prosthesis (21 CFR §888.3670); Class II

Prosthesis, Shoulder, Non-Constrained, Metal/Polymer, Cemented (21 CFR §888.3650); Class II

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

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

Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (21 CER §888.3690); Class II

Product Codes: MBF, KWT, KWS, PAO, HSD

Substantially Equivalent Predicate Devices: K060692 (Primary) - Comprehensive Primary Shoulder Stems, Biomet Manufacturing Corp.

K060694 - Modular Hybrid Glenoid, Biomet Manufacturing Corp.

K060716 - Versa-Dial Humeral Head Prosthesis, Biomet Manufacturing Corp.

K162024 - Altivate Anatomic Shoulder System, Encore Medical, L.P.

K111596 - Total Shoulder System, Shoulder Innovations, LLC

K091196 - Arthrosurface GRS™ Glenoid Resurfacing System, Arthrosurface, Inc.

K122698 - Aequalis Ascend Flex Shoulder System, Tornier SAS

K905786 – Global Total Shoulder, DePuy Inc.

K052472 – DePuy Global Shoulder Crosslink Glenoid, DePuy Orthopedics, Inc.

K121183 – Comprehensive Reverse Shoulder – E1 Polyethylene Claims, Biomet Manufacturing

Device Description:
The Ignite Anatomic Shoulder System is total shoulder arthroplasty system consisting of humeral heads (38 - 57mm diameters), offset taper adapters (multiple offsets), stems (66-82mm lengths), and glenoid components (multiple sizes).

The anatomic humeral construct consists of a wrought Cobalt-Chromium Humeral Head, a wrought Ti-6Al-4V Taper Adapter, and an additively manufactured Ti-6Al-4V Stem.

The All-Poly Anatomic Glenoid consists of Crosslinked Alpha-Tocopherol (Vitamin-E) infused Ultra-High-Molecular-Weight-Polyethylene. 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 Anatomic Shoulder System is intended for use in total or hemi-shoulder replacement procedures to address the following:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Revision where other devices or treatments have failed.

- Correction of functional deformity.
- Fracture of the humeral head.
- Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Fixation Methods
The humeral stem is intended for cemented or cementless use. The glenoid is intended for cemented use only.

Summary of Technologies:
The Ignite Anatomic Shoulder System is substantially equivalent to the predicate devices in terms of its intended use and indications, material, size ranges, and design intent. While there are minor differences, the non-clinical testing described in the next section demonstrated that the differences do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:
The following performance data were provided in support of a substantial equivalence determination of the subject device:

- Range of Motion Evaluation (ASTM F1378)
- Biocompatibility Assessments (ISO 10993-1)
- Porous Structure Characterization (ASTM F1044, ASTM F1147, ASTM F1160, ASTM F1978, ASTM F1854)
- Polyethylene Characterization
- Wear Testing (pristine and abrasive)
- Taper Pullout Testing (ASTM F2009)
- Construct Fatigue Testing
- Glenoid Loosening Testing (rocking horse - ASTM F2028)
- Glenoid Loosening Testing (static and cyclic torsional resistance)
- Glenoid Pullout Testing
- Shelf-Life Testing (ISO 11607-1 and ISO 11607-2)
- Sterilization Validation (ISO 11137-1 and ISO 11137-2)

Clinical Testing:
Clinical testing was not necessary to demonstrate substantial equivalence of the Ignite Anatomic Shoulder System to the predicate devices.

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.