Fix Surgical
℅ Jennifer Palinchik
President
JALEX Medical
27865 Clemens Road, Suite #3
Westlake, Ohio 44145

March 22, 2024

Re: K233148
Trade/Device Name: Augment Off-Axis Instrument System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: February 16, 2024
Received: February 20, 2024

Dear Jennifer Palinchik:

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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.03.22 13:19:54 -04'00'

for: Farzana Sharmin, PhD
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)*
K233148

Device Name
Augment Off-Axis Instrument System

Indications for Use *(Describe)*
The Augment Off-Axis Instrument System consists of specialized instruments intended to prepare anatomy prior to implantation of Comprehensive® Reverse Shoulder System components in reverse total shoulder arthroplasty procedures or Alliance® Augmented Glenoid System components in anatomic total shoulder arthroplasty procedures in accordance with their respective cleared indications for use and contraindications.

The instruments for this system are specifically indicated for use with the Comprehensive ® Reverse Shoulder System (K193373) or the Alliance® Augmented Glenoid System (K193180).

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

Applicant: Fix Surgical
425 Fayette Street, #617
Conshohocken, PA 19428

Date: 03/21/2024

Applicant Contact: Brian Karpinski, President
brian@fixsurgical.com

Contact Person: Jennifer Palinchik, President
Contact Email: jpalinchik@jalexmedical.com
Contact Telephone: (440) 935-3282
Contact Fax: (440) 933-7839

Regulation Number: 21 CFR §888.3660

Classification Product Code: PHX, KWS, KWT

Device Trade Name: **Augment Off-Axis Instrument System**
Device Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Device Common Name: Shoulder Prosthesis
Device Class: II
Reviewing Panel: Orthopedic

Primary Predicate Device: **K193373 – Comprehensive® Reverse Shoulder System**
Additional Predicates: K080642 – Comprehensive® Reverse Shoulder System
K193180 – Alliance® Augmented Glenoid System

Device Description:
The Augment Off-Axis Instrument System consists of specialized instruments that are designed for preparation of anatomy prior to implantation of Comprehensive® Reverse Shoulder System or Alliance® Augmented Glenoid System components. The instruments in this system are intended to provide an alternate approach in ensuring proper preparation of the glenoid bone and tissue for receipt of a glenoid implant augment in reverse and anatomic total shoulder arthroplasty procedures.

A drop-in instrument tray contains the Augment Off-Axis reusable surgical instruments for secure and ergonomic storage, sterilization, and transportation between uses.

Indications for Use:
The Augment Off-Axis Instrument System consists of specialized instruments intended to prepare anatomy prior to implantation of Comprehensive® Reverse Shoulder System components in reverse total shoulder arthroplasty procedures or Alliance® Augmented Glenoid System components in anatomic total shoulder arthroplasty procedures in accordance with their respective cleared indications for use and contraindications.

The instruments for this system are specifically indicated for use with the Comprehensive ® Reverse Shoulder System (K193373) and Alliance® Augmented Glenoid System (K193180).

Summary of Technological Characteristics:
The potential impact on substantial equivalence for each of the technological differences of the Augment Off-Axis Instrument System and the predicate Comprehensive® Reverse Shoulder System (K193373) and the Alliance® Augmented Glenoid System (K193180) instrument systems was addressed through verification and validation processes.

Collectively, the instruments of the subject Augment Off-Axis Instrument System have the same intended use and similar indications for use as predicate system instruments. Technological characteristics of the subject system are similar to those of the predicate, and the information provided herein demonstrates that any differences do not impact safety or effectiveness.

These aspects of the subject device were determined to be substantially equivalent to the predicates as the systems compare similarly in:

- Regulatory Characteristics and Intended Use/Indications for Use
- Device Function/Performance
- Materials and Manufacturing Processes
- Design Features/Dimensions
- Post-Processing Procedures, including Sterility and Shelf-Life Characteristics

Performance Data - Nonclinical:
Substantial equivalence is supported by the results of verification testing to confirm features, geometry, and performance of the Augment Off-Axis instruments, which support that the subject device performs as well as the predicate system instruments.

Clinical Testing:
Clinical testing was not required as a basis for substantial equivalence.

Conclusion:
Based upon a comparison of indications for use, designs, materials and sterilization method, performance characteristics, and operational principles, the components of the Augment Off-Axis System are substantially equivalent to those of the predicate devices identified in this premarket notification.