June 28, 2024

Accufix Surgical Inc.
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K240268
Trade/Device Name: Accu-Joint Hemi Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD

Dear Nathan Wright:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on February 29, 2024. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lixin Liu, OHT6: Office of Orthopedic Devices, 301-796-3480, Lixin.Liu@fda.hhs.gov.

Sincerely,

Lixin Liu -S

Lixin Liu, Ph.D.
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

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Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: January 31, 2024
Received: January 31, 2024

Dear Nathan Wright:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on February 29, 2024.

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,

Lixin Liu -S

Lixin Liu, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240268

Device Name

Accu-Joint Hemi Implant

Indications for Use *(Describe)*

The Accu-Joint Hemi Implant, a hemi-arthroplasty metatarsal head or phalangeal base implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock, along with the following clinical conditions: Hallux Limitus, Hallux Valgus, Hallux Rigidus, and an unstable or painful MTP joint. The Accu-Joint Hemi Implant is intended to be used with bone cement.

The metatarsal head and phalangeal base may not be used together at the same joint.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Submitter's Name:	Accufix Surgical Inc.
Submitter's Address:	Medical Center of West Haven 385 Main Street, Suite 10 West Haven, Connecticut 06516
Submitter's Telephone:	203-258-7082
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	January 31, 2024
Trade or Proprietary Name:	Accu-Joint Hemi Implant
Classification & Regulation #:	Class II per 21 CFR §888.3730
Regulation Name:	Toe Joint Phalangeal (Hemi-toe) Polymer Prosthesis
Product Code:	KWD
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Accu-Joint Hemi Implant consists of a hemi-arthroplasty metatarsal head or phalangeal base intended to resurface the metatarsophalangeal joint. These components are used for hemi-arthroplasty and are not used together to create a joint. The Accu-Joint Hemi Implant is designed with a threaded shaft for intramedullary insertion. The implant has a driver pocket on the articular surface axially aligned with the threaded shaft. To accommodate a wide range of patient anatomies, various sizes are offered.

The purpose of this submission is to offer a sterile packaged option of the Accu-Joint Hemi Implant.

INDICATIONS FOR USE

The Accu-Joint Hemi Implant, a hemi-arthroplasty metatarsal head or phalangeal base implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock, along with the following clinical conditions: Hallux Limitus, Hallux Valgus, Hallux Rigidus, and an unstable or painful MTP joint. The Accu-Joint Hemi Implant is intended to be used with bone cement.

The metatarsal head and phalangeal base may not be used together at the same joint.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences in sterility status do not raise any different issues of safety and effectiveness. The subject is provided EO sterilized to the end-user while the primary predicate is provided non-sterile requiring sterilization by the end user. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Material of Manufacture
- Structural Support Mechanism
- Mechanical Performance

Predicate Device

510k Number	Trade or Proprietary or Model Name	Manufacturer
K200951	Accu-Joint Hemi Implant	Accufix Surgical Inc.

Reference Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer
K203634	BioPoly Great Toe Hemiarthroplasty Implant	BioPoly, LLC
K222964	BioPoly Lesser Toe Hemiarthroplasty Implant	BioPoly, LLC

PERFORMANCE DATA

The Accu-Joint Hemi Implant EO sterilization process was validated per ISO 11135, and the sterile packaging was validated per ISO 11607-2, ASTM D4169, ASTM F1886, ASTM F88, and ASTM F1929. The mechanical testing screw testing per ASTM F543 and the dynamic bending testing performed on the Accu-Joint Hemi Implant System under K200951 established the substantial equivalence in mechanical performance and was not required for this submission because the sterilization changes do not affect mechanical performance.

CONCLUSION

The overall technology characteristics and the validation data lead to the conclusion that the Accu-Joint Hemi Implant is substantially equivalent to the predicate device.