December 8, 2020

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

Re: K200951
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
Dated: October 29, 2020
Received: October 28, 2020

Dear Nathan Wright:

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,

Ting Song, Ph.D., R.A.C.
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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K200951

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.

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5. 510(K) SUMMARY

Submitter's Name:	Accufix Surgical, Inc.
Submitter's Address:	Medical Center of West Haven 385 Main Street, Suite 10 West Haven, CT 06516
Submitter's Telephone:	203-258-7082
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	April 8, 2020
Trade or Proprietary Name:	Accu-Joint Hemi Implant
Common or Usual Name:	Hemi-toe Prosthesis
Classification:	Class II per 21 CFR §888.3730
Regulation Name:	Toe Joint Phalangeal (Hemi-Toe) Polymer Prosthesis
Product Code:	KWD
Classification Panel:	Division of Orthopedic Devices

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.

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 Accu-Joint Hemi Implant is manufactured from medical grade Ti-Al6-V4 per ASTM F136. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Technological characteristics
- Insertion Method
- Sizes
- Hole in articulating surface

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K190543, K102401, K070052, K023684	Cannulated Hemi Implant	Vilex in Tennessee, Inc.	Primary
K121973	Hemi-Edge Toe System	BioPro, Inc.	Additional

PERFORMANCE DATA

The Accu-Joint Hemi Implant has been tested in the following test modes:

- Static torsion per ASTM F543
- Driving torque per ASTM F543
- Static pullout per ASTM F543
- Dynamic Bending

The results of this non-clinical testing show that the strength of the Accu-Joint Hemi Implant is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

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