November 17, 2020

Armis Biopharma, Inc.
% Lynn C. Hansen
Director of Clinical and Regulatory Affairs
Pharmatech Associates, Inc.
22320 Foothill Blvd. Suite 330
Hayward, California 94541

Re: K202777
Trade/Device Name: VeriFixx™ Small Bone Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: September 21, 2020
Received: September 22, 2020

Dear Lynn C. Hansen:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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 below.

510(k) Number *(if known)*
K202777

Device Name
VeriFixx™ Small Bone Implant

Indications for Use *(Describe)*
The VeriFixx™ Small Bone Implant is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

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

Date:	November 12, 2020
Sponsor:	Armis Biopharma, Inc. 2950 East Harmony Road, Suite 252 Ft. Collins, CO 80528 Tel: 1-800-970-1779 Fax: 1-970-797-2721
Sponsor Contact:	Lynn C. Hansen, RAC Director of Clinical and Regulatory Affairs Pharmatech Associates E-mail: lhansen@pai-qbd.com Tel: 650-303-6003
Trade Names:	VeriFixx™ Small Bone Implant
Common Name:	Pin, Fixation, Smooth Implant
Classification Name	Smooth or threaded metallic bone fixation fastener
Regulation / Product Code:	21 CFR 880.3040 / HTY
Regulatory Class:	Class II
Device Description:	The VeriFixx™ SBI is single use, gamma sterilized device that is surgically implanted into the intramedullary canal of the bones in the toe to create a fusion and provides stability and maintain the alignment of bone during the healing process. The device is a solid, non-threaded implant that has a superior surface protrusion known as the dorsal fin, which is intended to maintain alignment of the joint during the healing process.
Indications for Use:	The VeriFixx™ Small Bone Implant is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.
Materials:	The VeriFixx™ SBI is comprised of polyether-ether-ketone (PEEK) which conforms to ASTM F2026 and coated with commercially pure (CP) titanium (ASTM F67).
Primary Predicate:	HammerFix™ (Extremity Medical, LLC) (K133636)
Secondary Predicate:	HammerTube™ (Paragon 28, Inc.) (K171715)

510(k) Summary

Performance Data:	The following bench tests were used to demonstrate equivalent performance of VeriFixx™ SBI to the predicate: insertion and pullout force testing, static and dynamic four-point bend testing, coating thickness characterization (ASTM F1854), surface roughness characterization, taber abrasion testing (ASTM F1978), and wear particle characterizations (ASTM F1877).
Technological Characteristics:	The VeriFixx™ SBI possesses the same technological characteristics as the predicate device. These include: • performance, • basic design, and • material. Differences between the VeriFixx™ SBI (non-threaded device, different sizes, CP Ti coating technology and presence of alignment fin) were shown not to raise new questions of safety or effectiveness. Therefore, the fundamental scientific technology of the VeriFixx™ SBI is similar to the predicate.
Conclusion:	The VeriFixx™ SBI possesses indications for use and technological characteristics similar to the predicate device. Therefore, the VeriFixx™ SBI is substantially equivalent to the predicate.