Intelivation
% Barry Sands
CEO and Founder
Rqmis
110 Haverhill Road
Suite 524
Amesbury, Massachusetts 01913

September 14, 2023

Re: K231147
Trade/Device Name: Hammerdesis™ Interphalangeal Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: August 8, 2023
Received: August 16, 2023

Dear Mr. Sands:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.09.14 16:21:29 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K231147

Device Name
Hammerdesis™ Interphalangeal Fusion System

Indications for Use *(Describe)*
The Hammerdesis™ Interphalangeal Fusion System is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges.

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

Intelivation's Hammerdesis™ Interphalangeal Fusion System

Date Prepared: September 13, 2023

I. Submitter, Author, and Contact Person

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II. Subject Device

Trade/proprietary name of device:	Hammerdesis™ Interphalangeal Fusion System
Common or Usual Name:	Counter rotational ring (sm/lg), K-wire
Classification Name:	Pin, Fixation, Smooth
Regulation Number:	888.3040 - Smooth or threaded metallic bone fixation fastener
Classification:	Class II
Product Code:	HTY

III. Predicate Device

Primary Predicate:

510(k) Number:	K190287
Trade/proprietary name of device:	Arthrex DynaNite PIP (Hammertoe) Implant
Applicant:	Arthrex Inc.
Regulation Number:	888.3040 - Smooth or threaded metallic bone fixation fastener
Classification:	Class II
Product Code:	HTY

Reference Device:

510(k) Number:	K131459
Trade/proprietary name of device:	AAP K-Wire, Steinmann Pin, Cerclage Wire
Applicant:	AAP Implantate AG
Regulation Number:	888.3040 - Smooth or threaded metallic bone fixation fastener
Classification:	Class II
Product Code:	JDW (subsequent code: HTY)

510(k) Number:	K191243
Trade/proprietary name of device:	HEDRON Cervical Spacers
Applicant:	Globus Medical Inc.
Regulation Number:	888.3080 Intervertebral body fusion device
Classification:	Class II
Product Code:	ODP, OVE

510(k) Number:	K192417
Trade/proprietary name of device:	ARIX Cannulated Screw System
Applicant:	Jeil Medical Corporation
Regulation Number:	888.3040: Smooth or threaded metallic bone fixation fastener
Classification:	Class II
Product Code:	HWC

IV. Device Description

The Hammerdesis™ Interphalangeal Fusion system is composed of a counter rotation ring implant, recovery dowel and K-wire to be used in conjunction with a peg and hole fusion of the phalanges. The implant comes in two different sizes to accommodate differing anatomies. The

counter rotation ring has axial spikes that prevent either side of the joint from rotating and allow fusion of the joint.

V. Indications for Use

The Hammerdesis™ Interphalangeal Fusion System is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges.

VI. Technological Characteristics

The Hammerdesis™ Interphalangeal Fusion System is composed of a counter rotation ring (small or large), recovery dowel and K-wire. The subject device implants are composed of Ti-6Al-4V per ASTM F3001-14 and stainless steel per ASTM F138.

The manufacturer produces all instrumentation from surgical grade stainless steel per traditional manufacturing methods.

VII. Performance Data

The subject Hammerdesis™ Interphalangeal Fusion System was evaluated in static torsion test, static and dynamic cantilever bend testing, and axial pullout. The subject device demonstrated superior performance in comparison to that of the predicate (K131459); therefore, the subject device mechanical performance is considered substantially equivalent to the predicate (K131459).

VIII. Sterility

The Hammerdesis™ Interphalangeal Fusion System is provided non-sterile and is intended to be end-user sterilized before use.

IX. Conclusion

The technological differences between the subject device and the primary (K190287) and reference predicates (K131459, K191243, K192417) do not raise new questions of safety and effectiveness. Any differences in technological characteristics have been tested and documented. The subject device and predicates (K190287, K131459, K191243, K192417) have been determined to be substantially equivalent in terms of indications for use, materials, performance, sterility, and biocompatibility.