August 5, 2020

Ilion Medical Inc
% Tania Fuentes-Davitt, Ph.D.
Quality Assurance & Regulatory Affairs, Director
825 Nicollet Mall, Suite 715
Minneapolis, Minnesota 55402

Re: K190580
Trade/Device Name: NADIA SI Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: July 28, 2020
Received: July 31, 2020

Dear Dr. Fuentes-Davitt:

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,

for Colin O'Neill, M.B.E.
Acting 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: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*
K190580

Device Name
NADIA SI Fusion System

Indications for Use *(Describe)*
The NADIA SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The purpose of this submission is to gain initial marketing authorization in the United States.

510(k) Number:	K190580
Date of Summary:	July 21, 2020
Applicant:	Ilion Medical, Inc Medical Arts Building 825 Nicollet Mall #715 Minneapolis MN, USA 55402
Applicant Contact (Primary):	Tania Fuentes Davitt, PhD, QA&RA mailto:taniafd@ilionmedical.com Tel: 952-200-04441
Applicant Contact (Secondary):	Betty Fuentes, CEO mailto:bfuentes@ilionmedical.com Tel: 612-332-2324
Proprietary Name:	NADIA SI Fusion System
Common Name:	Sacroiliac joint fusion device
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3040
Classification Panel:	Orthopedic
Product Code	OUR
Predicate Device (Primary):	Tenon Medical – Catamaran (K180818)
Predicate Device (Additional):	Globus – SI-LOK (K112028) Medtronic – RIALTO (K161210) Synthes Cannulated Screw (K021932)

Product Description:

The NADIA SI Fusion System is intended to provide support and structural stability during sacroiliac fusion surgery.

The NADIA sacroiliac (SI) fusion system consist of different sizes of lattice fenestrated screws that accept cannulated instruments. NADIA screws are manufactured from titanium alloy per ASTM F136 and will be provided gamma sterilized. The screws are available in multiple lengths and diameters and are provided either uncoated or coated with hydroxyapatite.

Instrumentation necessary for proper implantation is also included.

Indication for Use:

The NADIA SI Fusion System is for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Technological Characteristics

The subject device was shown to be substantially equivalent to its legally-marketed predicates in terms of design, intended use, material composition, function, and range of sizes.

Performance Testing

Non-Clinical Testing

The following mechanical tests were performed to support substantial equivalence of the NADIA SI Fusion System:

ASTM F543-13, Annex 2: Driving Torque
ASTM F543-13, Annex 1: Torsional Failure
ASTM F543-13, Annex 3: Pushout Strength
ASTM F2077-14: Compression Shear Fatigue
Test ASTM F1264-16: Bending Fatigue Test

Clinical Testing

Clinical data was also provided to support a substantially equivalent safety and effectiveness profile compared to the predicate.

Conclusion

Based on the performance data, and technological characteristics, the NADIA SI Fusion System is substantially equivalent to its legally-marketed predicate.