June 6, 2025

Omnia Medical, LLC
% Jennifer Palinchik
Owner & CEO
SageMar Medical, LLC
30628 Detroit Rd., #254
Westlake, Ohio 44145

Re: K242431
Trade/Device Name: Omnia Medical PsiF DNA™ System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: June 3, 2025
Received: June 3, 2025

Dear Jennifer Palinchik:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

STEPHANIE SMITH -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242431

Device Name

Omnia Medical PsiF DNA™ System

Indications for Use *(Describe)*

The Omnia Medical PsiF DNA™ System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions. The PsiF DNA™ may be implanted via a transverse or inline approach. When PsiF DNA™ is implanted inline, it must be used with a PsiF DNA™ screw implanted transversely across the same sacroiliac 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.

510(k) Summary

Submitted By:	Omnia Medical, LLC 6 Canyon Road Suite 300 Morgantown, WV 26508
Date:	06/03/2025
Contact Person:	Jennifer Palinchik
Contact Telephone:	(440) 935-3282
Device Trade Name:	Omnia Medical PsiF DNA™ System
Device Classification Name:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	OUR
Predicate Devices:	Primary: SAIL Fusion, LLC BowTie™ SI Joint Fusion System (K232149) Additional: Synthes 6.5 mm Cannulated Screw (K021932)

Device Description:

The Omnia Medical PsiF DNA™ System consists of screws and washers manufactured from Ti-6Al-4V ELI per ASTM F3001 and ASTM F136, respectively. The screws are available in one diameter and a variety of lengths to accommodate varying patient anatomy. The system includes instrumentation for implantation that is manufactured from surgical grade stainless steel or aluminum. During the procedure, the implant is inserted through the ilium to pierce its medial cortex, across the sacroiliac joint and into the sacrum to pierce its lateral cortex, and bone graft material is placed in the barrel of the implant to facilitate additional bone incorporation after surgery. The implants and instruments are provided in two surgical kit options. In one kit, the implants and instruments are provided non-sterile and sterilized by the end user. In the other kit, the implants and instruments are single-use and provided sterile.

Indications for Use:

The Omnia Medical PsiF DNA™ System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions. The PsiF DNA™ may be implanted via a transverse or inline approach. When PsiF DNA™ is implanted inline, it must be used with a PsiF DNA™ screw implanted transversely across the same sacroiliac joint.

Comparison of Technological Characteristics with Predicate devices:

The Omnia Medical PsiF DNA™ System and the predicates have the same intended use and fundamental scientific technology. A comparison table of the subject device and predicate devices technological characteristics is provided in this submission. There are no differences in technological characteristics that raise new questions of safety and efficacy.

Non-Clinical Testing:

Substantial equivalence is supported by the results of mechanical testing including:

- Static three-point bending per ASTM F2193
- Dynamic three-point bending per ASTM F2193
- Screw axial pullout per ASTM F543
- Static driving torque per ASTM F543
- Static torsion per ASTM F543
- Static Vertical Shear ASTM F3574
- Dynamic Vertical Shear ASTM F3574

Mechanical testing methods, data, and reports are provided in this submission. Substantial equivalence is also supported by the results of cadaveric testing. Testing methods, data, and reports are provided in this submission.

Clinical Testing:

Clinical testing was not required to support a substantial equivalence determination for the PsiF DNA™ device. The mechanical testing results, material, indications and intended uses, and device function are comparable to the predicate device.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate devices, the subject devices have demonstrated substantial equivalence.