October 27, 2023

HT Medical LLC dba Xenix Medical
Teresa Cherry
VP of Quality and Regulatory
111 W Jefferson St
Suite 100
Orlando, Florida 32801

Re: K233241
Trade/Device Name: SOLACE Sacroiliac Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC, OLO
Dated: September 28, 2023
Received: September 28, 2023

Dear Teresa Cherry:

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.

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,

Colin O'neill -S

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)*
K233241

Device Name
SOLACE Sacroiliac Fixation System

Indications for Use *(Describe)*

The SOLACE Sacroiliac Fixation System is indicated for sacroiliac joint fusion for:
• Sacroiliac joint dysfunction including degenerative sacroiliitis and sacroiliac joint disruptions
• Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The SOLACE Sacroiliac Fixation System is also indicated for fracture fixation of acute, non-acute, and nontraumatic fractures involving the sacroiliac joint.

The SOLACE Sacroiliac Fixation System Navigation Instruments are intended to be used with the SOLACE Sacroiliac Fixation System during surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System S8, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name:	SOLACE Sacroiliac Fixation System
Manufacturer:	HT Medical, LLC d.b.a. Xenix Medical 111 W Jefferson St., Suite 100 Orlando, FL 32801
Contact:	Teresa Cherry Vice President of Quality Assurance and Regulatory Affairs Xenix Medical Phone: 888.594.8633
Prepared by:	Teresa Cherry HT Medical, LLC d.b.a Xenix Medical 111 W Jefferson St., Suite 100 Orlando, FL 32801 Phone: 407.785.4216 tcherry@xenixmedical.com
Date Prepared:	October 26, 2023
Classifications:	21 CFR §888.3040; Smooth or threaded metallic bone fixation fastener 21 CFR §888.4560; Stereotaxic Instruments
Class:	II
Product Codes:	OUR, HWC, OLO
Device Common Name:	Sacroiliac Joint Screw, Orthopedic Stereotaxic Instrument

Indications for Use:

The SOLACE Sacroiliac Fixation System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including degenerative sacroiliitis and sacroiliac joint disruptions
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Device Description:

The SOLACE Sacroiliac Fixation System consists of 3D printed medical grate Titanium Alloy Implants (Ti-6Al-4V ELI per ASTM F-3001) and surgical instrumentation for implantation. Implants are provided sterile in various lengths and diameters. The reusable instrumentation is provided non-sterile in a steam sterilization instrument tray.

Devices incorporate Xenix Medical's proprietary NANOACTIV micro and nano-roughened surface designed to improve fixation to adjacent bone. The SOLACE implant surfaces have been engineered with surface features at a nanometer (10^{-9}) level, which have demonstrated the ability to elicit an endogenous cellular and biochemical response as represented by mineralization in human mesenchymal stem cells *in vitro*. The implant surface demonstrates elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document.

Predicate Devices:

Table 1: Predicate Devices

Device Name(s)	Manufacturer	K-Number
Primary Predicate Device		
Xenix Medical Sacroiliac Fixation System	HT Medical, LLC d.b.a Xenix Medical	K231829
Reference Device – for nano claims		
neoWave C, neoWave LS, and Ti3D Cervical	HT Medical, LLC d.b.a Xenix Medical	K222988

Summary of Substantial Equivalence:

The SOLACE Sacroiliac Fixation System implants described and cleared in 510(k) number K231829, serves as the predicate device for this premarket notification. There are no changes to the implants as cleared in K231829; the subject of this Special 510(k) has the same intended use/indications for use, same device design, same manufacturing process, same cleaning, packaging and sterilization. The subject for this premarket notification is the addition of nano claims as cleared in K222988. Therefore, the SOLACE Sacroiliac Fixation System is substantially equivalent to the predicate device currently cleared under K231829.

Summary of Verification and Validation Activities:
In consideration of the FDA's Guidance for Industry: Considering Whether an FDA-Related Product Involves the Application of Nanotechnology, imaging studies were performed to assess that the deliberately modified NANOACTIV surface on the implants results in micro and nano surface roughness ranging in size between 1-100 nanometers and are equivalent to the surfaces as cleared in K222988. An *in vitro* study provided in K222988 demonstrated that the modified nanosurface supported differentiation of mesenchymal stem cells through the osteogenic lineage and production of a mineralized matrix as compared to non-treated surfaces.

Conclusion:
Based on the information provided in this Special 510(k), the SOLACE Sacroiliac Fixation System implants are substantially equivalent to the identified predicate device and the reference device as cleared under K231829 (and K222988).