August 15, 2023

HT Medical d.b.a. Xenix Medical
℅ Justin Eggleton
Vice President, Regulatory Affairs
Mcra LLC
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20001

Re: K231829
Trade/Device Name: Xenix Medical 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, OLO, HWC
Dated: June 21, 2023
Received: June 21, 2023

Dear Justin Eggleton:

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,

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)*
K231829

Device Name
Xenix Medical Sacroiliac Fixation System

Indications for Use *(Describe)*
The Xenix Medical 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 Xenix Medical Sacroiliac Fixation System is also indicated for fracture fixation of acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

The Xenix Medical Sacroiliac Fixation System Navigation Instruments are intended to be used with the Xenix Medical 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.

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510(k) Summary

Device Trade Name:	Xenix Medical Sacroiliac Fixation System
Manufacturer:	HT Medical 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:	Mr. Justin Eggleton Vice President, Regulatory Affairs MCRA, LLC 803 7th Street NW, 3rd Floor Washington, DC 20001 jeggleton@mcra.com Phone: 202-552-5804
Date Prepared:	August 15, 2023
Classifications:	21 CFR §888.3040; Smooth or threaded metallic bone fixation fastener 21 CFR §882.4560; Stereotaxic Instruments
Class:	II
Product Codes:	OUR, OLO, HWC
Device Common Name:	Sacroiliac Joint Screw, Orthopedic Stereotaxic Instrument

Indications for Use:

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

The Xenix Medical Sacroiliac Fixation System Navigation Instruments are intended to be used with the Xenix Medical 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.

Device Description:

The Xenix Medical Sacroiliac Fixation System consists of 3D printed medical grade 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.

Predicate Devices:

Table 1: Predicate Devices

Device Name(s)	Manufacturer	K-Number
Primary Predicate Device		
iFuse TORQ Implant System	SI-Bone	K222605
Additional Predicate Devices		
Rialto™ SI Fusion System	Medtronic	K161210
Sacrix Sacroiliac Fixation (SacroFuse/SIJFuse)	SpineFrontier (Sacrix)	K150017
Synthes 6.5mm Cannulated Screw	Synthes	K021932
Reference Device		
Quantum Anterior Cervical Plate (for manufacturing reference)	Nvision Biomedical Technologies, Inc	K210424

Performance Testing Summary:

Mechanical testing, including static and dynamic cantilever bending and axial pull-out, were conducted in accordance with ASTM F2193 and ASTM F543 to demonstrate substantial equivalence of the subject Xenix Medical Sacroiliac Fixation System Implants to the predicate devices. Sterilization validation of the subject implants was performed in accordance with ISO 11137-1 and ISO 11137-2. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72.

Accuracy testing was performed on the Xenix Medical Sacroiliac Fixation System Navigation instruments to confirm that the instruments register and function properly with the Medtronic StealthStation S8 Navigation System. Dimensional analysis of the Xenix Medical Sacroiliac Fixation System Navigation instruments was performed against the predicate instruments.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate cited in the passage above with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:
The Xenix Medical Sacroiliac Fixation System is substantially equivalent to the cited predicate devices with respect to intended use, indications for use, design, function, materials, and performance. The differences in the technological characteristics between the subject device and the predicate devices do not raise new or different questions of safety and effectiveness.