June 12, 2025

HT Medical d.b.a. Xenix Medical
Tyler Holschlag
Vice President Product Development
111 W Jefferson St., Suite 100
Orlando, Florida 32801

Re: K251154
Trade/Device Name: RIVA Posterior Fixation System; RIVA Posterior Fixation System Navigation Instruments
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, OLO
Dated: April 8, 2025
Received: April 14, 2025

Dear Tyler Holschlag:

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,

EILEEN CADEL -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.

510(k) Number *(if known)*
K251154

Device Name
RIVA Posterior Fixation System;
RIVA Posterior Fixation System Navigation Instruments

Indications for Use *(Describe)*
The Xenix Medical RIVA Posterior Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system or anterolateral fixation, in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine:
• Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).
• Spondylolisthesis
• Trauma (i.e. fracture or dislocation).
• Spinal Stenosis
• Deformities or curvatures (i.e scoliosis, kyphosis, and/or lordosis)
• Tumor
• Pseudoarthrosis
• Failed previous fusion

Xenix Medical fenestrated screws are intended to be used with saline or radiopaque dye.

Xenix Medical RIVA Posterior Fixation System Navigation Instruments are intended to be used with the Xenix Medical RIVA Posterior 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™ S8 System, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the 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.

510(k) Summary

Device Trade Name:	RIVA Posterior Fixation System
Manufacturer:	HT Medical d.b.a Xenix Medical 111 W Jefferson St., Suite 100 Orlando, FL 32801
Contact:	Tyler Holschlag Vice President of Product Development Xenix Medical
Date Prepared:	June 12, 2025
Classifications:	21 CFR §888.3070; Thoracolumbosacral pedicle screw system 21 CFR §888.3060; Spinal intervertebral body fixation orthosis 21 CFR §882.4560; Stereotaxic Instruments
Class:	II
Product Codes:	NKB, KWQ, OLO

Indications for Use:

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Device Description:

The Xenix Medical RIVA Posterior Fixation System is a non-cervical spinal fixation system used to build constructs within the body to act as temporary or permanent non-cervical spinal fixation devices and is intended for use as a posterior pedicle screw fixation system, and/or an anterolateral fixation system to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusion to occur.

The Xenix Medical RIVA Posterior Fixation System includes a variety of single-use implants manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and/or cobalt chrome alloy (Co-28Cr-6Mo per ASTM F1537 or Co-35Ni-20Cr-10Mo per ASTM F562) and is comprised of polyaxial pedicle screws, as well as connecting spinal rods, connectors, crossbars, and a separate set screw locking element. The instruments included in the Xenix Medical RIVA Posterior Fixation System facilitate the placement, adjustment, final locking, and removal, if necessary, of the system implants, and accessories to the system include trays and caddies for storage, protection, and organization prior to and during the steam sterilization process.

Predicate Devices:

Device Name(s)	Manufacture	K-Number
Primary Predicate		
Primus Spinal Fixation System	Spinal Elements	K243916
Additional Predicate Devices		
Atlas Spine Pedicle Screw System	Atlas Spine	K112759
Mariner Pedicle Screw System	SeaSpine	K212692
Medtronic CD Horizon	Medtronic	K140454

Performance Testing Summary:

The Xenix Medical RIVA Posterior Fixation System demonstrated substantially equivalent mechanical performance to the predicate devices through static and dynamic compression bending, static torsion, axial and torsional grip, tulip shank dissociation, and flexion-extension with reference to ASTM F1717 and ASTM F1798.

Accuracy testing was performed on the Xenix Medical RIVA Posterior Fixation System Navigation instruments to confirm that the instruments register and function properly with the Medtronic® StealthStation™ System. Dimensional analysis of the Xenix Medical RIVA Posterior 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 RIVA Posterior 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.