PIUR Imaging GmbH
% Jennifer Willner
President
JW Regulatory Consulting LLC
406 Wacouta St, Suite 417
Saint Paul, Minnesota 55101

June 30, 2025

Re: K250484
Trade/Device Name: PIUR tUS inside
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 29, 2025
Received: May 29, 2025

Dear Jennifer Willner:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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)*

K250484

Device Name

PIUR tUS inside

Indications for Use *(Describe)*

PIUR tUS inside System is a computer-aided detection device intended to assist and support medical professionals in the diagnostic workflow of thyroid and thyroid nodules acquired from FDA-cleared ultrasound systems, including image documentation, analysis, and reporting. The device supports the physician with additional information during image review, including quantification and visualization of sonographic characteristics of thyroid nodules.

PIUR tUS inside System may be used on any adult patient aged 22 and older, independent of gender, linguistic and cultural background, or health status, unless any of the contraindications apply.

The PIUR tUS inside System acts as part of the diagnostic chain and must not be used as a sole source for treatment decisions, but as an add-on solution to regular 2D ultrasound imaging.

The PIUR tUS inside System is not intended for body contact (including skin, mucosal membrane, breached or compromised surfaces, blood path indirect, tissues, bones, dentin, or circulation blood).

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

510(k) Number: K250484

Date Prepared: June 27, 2025

Table 1: Submitter Information

Manufacturer: PIUR Imaging GmbH Kaiserstrasse 8/1/11 1050 Vienna Austria US FDA ERN: Pending	Manufacturer's Contact Person: Milos Stojanovic Quality & Regulatory Affairs Manager Phone: +43 681 815 912 47 Email: stojanovic@piurimaging.com

Table 2: Device Information

Trade Name	PIUR tUS inside
Common Name	PIUR tUS inside
Classification Name	Picture Archiving and Communications System
Regulation	21 CFR 892.2050
Product Code	QIH
Regulatory Classification:	Class II
Device Panel:	Radiology (OHT8)

The PIUR tUS inside System is substantially equivalent to the previously cleared predicate PIUR tUS Infinity (**Table 3**). Neither of these have been subject to a design-related recall.

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
PIUR tUS Infinity	PIUR Imaging GmbH	K240036

Device Description

PIUR tUS inside is a medical device which enhances standard ultrasound devices with a three-dimensional (3D) tomographic imaging method for a 3D analysis of ultrasound volumes. With PIUR tUS inside, examining physicians can make diagnostic decisions based on standard 2D as well as 3D image data integrated in an ultrasound device environment. This 3D data provides information which previously could have only been generated using other 3D imaging technologies like CT or MRI.

The PIUR tUS inside runs on a compatible GE Healthcare ultrasound system. The PIUR tUS inside takes as an input a sequence of 2D ultrasound images that are transmitted through a software interface from the ultrasound to the PIUR tUS inside. In addition, the PIUR Sensor must be clipped onto the ultrasound transducer using individually designed PIUR Brackets. For image acquisition, the user moves the 2D ultrasound transducer perpendicular to the structure to be imaged over the region of interest of the patient's body. An inertial measurement unit (IMU),

which is built into the PIUR Sensor, tracks the orientation of the transducer during the scan and sends this information to the ultrasound via Bluetooth.

The PIUR tUS inside combines image information and sensor information to generate tomographic 3D ultrasound volumes on which image analysis can be performed. An important property of this method is the unlimited length of the acquired volume. PIUR tUS inside therefore allows recording and analyzing a complete thyroid lobe.

The PIUR tUS inside and the PIUR tUS Infinity Predicate Device share most hardware and software components and algorithms. On the hardware side, both systems use the same PIUR Sensor to track probe movement during a freehand ultrasound acquisition. The data from the PIUR Sensor is transferred wirelessly through a Bluetooth connection to the software where it is being used to generate ultrasound volumes from the freehand sweep. Both systems also share the same volume compounding software algorithms, semi-automatic lobe and nodule segmentation algorithms, and volume calculation algorithms. The performance for image compounding and volume calculations are therefore the same for both systems.

The main difference between the PIUR tUS inside System and the Predicate Device is the interface for image retrieval. While the Predicate Device uses the Infinity Box to transfer digital ultrasound images from a third-party ultrasound system to the software through a Wi-Fi connection, the PIUR tUS inside has direct access to the image stream through a software interface. It runs directly on the compatible ultrasound scanners: GE Healthcare LOGIQ E10 (K231966) and GE Healthcare LOGIQ E10s/Fortis (K231989). This, however, is not performance relevant as the image data remains the same. It only reduces the number of compatible ultrasound systems as a close collaboration with the ultrasound manufacturer is required.

The PIUR tUS inside System acts as part of the diagnostic chain only and must not be used as a sole source for diagnostic or treatment decisions.

The solution is intended to be used on patients aged 22 and older, independent of gender, linguistic and cultural background, or health status, unless any of the contraindications apply, in a non-sterile environment. The solution is not intended to be used on patients with open wounds or irritated skin or during surgery.

Indications for Use

PIUR tUS inside System is a computer-aided detection device intended to assist and support medical professionals in the diagnostic workflow of thyroid and thyroid nodules acquired from FDA-cleared ultrasound systems, including image documentation, analysis, and reporting. The device supports the physician with additional information during image review, including quantification and visualization of sonographic characteristics of thyroid nodules.

PIUR tUS inside System may be used on any adult patient aged 22 and older, independent of gender, linguistic and cultural background, or health status, unless any of the contraindications apply.

The PIUR tUS inside System acts as part of the diagnostic chain and must not be used as a sole source for treatment decisions, but as an add-on solution to regular 2D ultrasound imaging.

PIUR tUS inside System is not intended for body contact (including skin, mucosal membrane, breached or compromised surfaces, blood path indirect, tissues, bones, dentin, or circulation blood).

Technological Characteristics

The PIUR tUS inside system provides the following functions:

- Use of ultrasound image post-processing to aid in the diagnosis of thyroid diseases.
- Operates in combination with hardware to generate 3D volumes. The PIUR Sensor is connected to the ultrasound transducer to detect probe movement for spatial 3D information. This use of hardware allows for reduced inter- and intra-observer variability compared to 2D ultrasound.
- Provides volumetric information as diagnostic output for the thyroid lobe and nodule as additional information. This includes nodule volume, which can be important for evaluating nodule growth over time.

Performance Standards

PIUR tUS inside has been developed in conformance with the following standards and FDA guidance, as applicable:

- ISO 13485:2016, Quality management systems – Requirements for regulatory purposes
- ISO 14971:2019, Medical devices – Application of risk management to medical devices
- IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 62304:2015, Medical device software – Software lifecycle processes
- IEC 82304-1:2016, Health Software Part 1: General Requirements for Product Safety
- EN 301 489-1 V2.2.3 (2019-11) – Electromagnetic compatibility (EMC) standard for radio equipment and services; Part I: common technical requirements; Harmonized standard covering essential requirements of article 3.1b of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
- EN 301 489-17 V3.2.4:2020 – Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
- IEC 60601-1:2013 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014 – Medical electrical equipment General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
- IEC 60601-2-37:2016 – Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- ISO 15223-1:2021, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- IEC 60417:2002, Graphical symbols for use on equipment
- NEMA PS 3.1-3.20:2023, Digital Imaging and Communications in Medicine (DICOM)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, September 2023
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data – Premarket Notification [510(k)] Submissions, September 2022

PIUR tUS inside has been designed to meet cybersecurity requirements using design vulnerability assessments utilizing the Common Vulnerability Scoring System (CVSS), providing open source and 3rd party libraries in the SBOM's and performing gray box penetration testing.

Performance Data

The PIUR tUS inside system complies with DICOM (Digital Imaging and Communications in Medicine), developed by the American College of Radiology and the National Electrical Manufacturers Association – NEMA PS 3.1-3.20.

PIUR Imaging conducted performance validation testing along with software verification and validation testing of the PIUR tUS inside System. Software performance, verification and validation testing demonstrated that the PIUR tUS inside System met all design requirements and specifications.

Electrical safety and EMC testing were conducted on the PIUR tUS inside. The testing complies with the applicable sections of IEC 60601-1:2013, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for the basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests,* and IEC 60601-2-37:2016, *Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*. An additional white-noise test verified that the use of the wireless PIUR tUS inside equipment does not induce any additional white noise band in the ultrasound image, and therefore, does not degrade the quality of ultrasound images.

Together with software verification and validation, safety and performance testing demonstrated that PIUR tUS inside system satisfies all design requirements and device specifications and is substantially equivalent to the Predicate Device.

Substantial Equivalence

In comparison with the Predicate Device (K240036), the PIUR tUS inside System has the same intended use / indications, technological characteristics and principles of operation as described in the comparison table below.

Table 4: Substantial Equivalence Comparison Table

Description	Subject Device	Predicate Device (K240036)
Product Name	PIUR tUS inside	PIUR tUS Infinity
Manufacturer	PIUR Imaging GmbH	PIUR Imaging GmbH
Product Code / Regulation	QIH / 21CFR 892.2050	QIH / 21CFR 892.2050
Indications for Use	PIUR tUS inside is a computer-aided detection device intended to assist and support the medical professionals in the diagnostic workflow of thyroid and thyroid nodules acquired from FDA-cleared ultrasound systems, including image documentation, analysis, and reporting. The device supports the physician with additional information during image review, including quantification and visualization of sonographic characteristics of thyroid nodules. PIUR tUS inside may be used on any adult patient aged 22 and older, independent of gender, age, linguistic and cultural background, or health status, unless any of the contraindications apply. PIUR tUS inside device is not intended for body contact (including skin, mucosal membrane, breached or compromised surfaces, blood path indirect, tissues, bones, dentin, or circulation blood).	PIUR tUS Infinity is a computer-aided detection device intended to assist and support the medical professionals in the diagnostic workflow of thyroid and thyroid nodules acquired from FDA-cleared ultrasound systems, including image documentation, analysis, and reporting. The device supports the physician with additional information during image review, including quantification and visualization of sonographic characteristics of thyroid nodules. PIUR tUS Infinity may be used on any adult patient aged 22 and older, independent of gender, age, linguistic and cultural background, or health status, unless any of the contraindications apply. PIUR tUS Infinity device is not intended for body contact (including skin, mucosal membrane, breached or compromised surfaces, blood path indirect, tissues, bones, dentin, or circulation blood).

Description	Subject Device	Predicate Device (K240036)
Functional Capability of Image Processing	The device performs 2D to 3D reconstruction to generate volumetric data of a thyroid. User-selected computer vision and machine learning algorithm suggested volumes of thyroid lobe and nodules are visualized to be confirmed by user. Based on that segmentation, quantification of nodules for sonographic characteristics (hyperechoic foci, echogenicity, texture, margin, orientation and anechoic areas) is being performed and visualized.	Same
Image Retrieval Interface	Direct access to the image stream through the software interface run directly on the compatible ultrasound scanner	Infinity Box transfers digital image from 3rd Party ultrasound system to the software through WiFi connection
Reading Paradigm	Device provides quantification and visualization of sonographic characteristics based on 3D volumetric data. Results provide proposals to be reviewed and confirmed by physicians.	Same
ACR TI-RADS Classification	Manual approach whereby user classifies 5 ACR TI-RADS parameters	Same
Output Generated by the Device	The device can export volumetric data, annotated screenshots and reports. Report can contain both sides of the patient and includes all relevant diagnostic information.	Same
Type of Film to be Processed by the Device	Digital ultrasound videoclip (cineloop)	Same
Software Design	Based on computer vision, machine learning, pattern recognition and quantification method.	Same
Ground Truth Establishment	The ground truth to be established for performance studies of the device are annotated data sets labeled by medical specialists.	Same
Platform	Windows-based	Same
Operating System	Ultrasound System	Standard PC or review station

Description	Subject Device	Predicate Device (K240036)
Clinical Application	Thyroid Lesions	Same
Image Type	Ultrasound volume image	Same
Image Format	DICOM format: Secondary Capture Image Storage - 1.2.840.10008.5.1.4.1.1.7 Multi-frame Grayscale Byte Secondary Capture Image Storage - 1.2.840.10008.5.1.4.1.1.7.2 Multi-frame True Color Secondary Capture Image Storage - 1.2.840.10008.5.1.4.1.1.7.4 Refer to: DICOM-Conformance Statement-PIUR tUS inside System	Same
ROI Quantification	Yes	Same
Automatically Generating Report	Yes	Same
Performance Testing Data to Support SE Determination	Results from standalone performance testing of machine learning algorithm suggested ROIs of user-selected nodules	Same
Device Components	PIUR Sensor PIUR Bracket inside Software	Infinity Box PIUR Sensor PIUR Bracket Infinity Software
DICOM Compliance	Yes	Same
Data Acquisition	Acquire medical image data from DICOM compliant Ultrasound imaging device	Same
Data / Image Types	Ultrasound image via DICOM format	Same

Conclusions

The PIUR tUS inside system performs as intended and presents no unacceptable risks to the intended patient population. The performance testing supports the safety of the device and demonstrates that the PIUR tUS inside system performs as intended in the specified use conditions. The PIUR tUS inside system is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed Predicate Device (K240036).