



PIUR Imaging GmbH  
% Jennifer Willner  
JW Regulatory Consulting LLC  
406 Wacouta St, Suite 417, St. Paul  
MN 55101  
USA

September 20, 2024

Re: K240036

Trade/Device Name: PIUR tUS Infinity  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical Image Management And Processing System  
Regulatory Class: Class II  
Product Code: QIH  
Dated: August 22, 2024  
Received: August 22, 2024

Dear Milos Stojanovic:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a faint, light blue watermark of the FDA logo.

**Jessica Lamb, Ph.D.**

Assistant Director

Imaging Software Team

DHT 8B: Division of Radiological Imaging  
Devices and Electronic Products

OHT 8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K240036

Device Name

PIUR tUS Infinity

Indications for Use (Describe)

PIUR tUS Infinity 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 Infinity 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 Infinity 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 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).

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.

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## 510(K) SUMMARY

510(k) Number: K240036

Date Prepared: September 20, 2024

**Table 1: Submitter Information**

Manufacturer: PIUR Imaging GmbH Hamburgerstr. 11/Top 7 1050 Vienna Austria US FDA ERN: Pending	Manufacturer's Contact Person: Jennifer Willner President JW Regulatory Consulting LLC Phone: +1 (612) 240-8904 Email: <a href="mailto:Jennifer@JWRegulatoryConsulting.com">Jennifer@JWRegulatoryConsulting.com</a>
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**Table 2: Device Information**

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

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

**Table 3: Predicate Devices**

<b>Predicate Device</b>	<b>Manufacturer</b>	<b>FDA 510(k)</b>
AmCAD-UT	AmCad BioMed Corporation	K203555

## Device Description

PIUR tUS Infinity is a computer-aided solution to aid in the diagnostic workflow of thyroid and thyroid nodules, including image documentation, analysis, and reporting. Computer vision and machine learning algorithms are applied to a sequence of ultrasound images of the thyroid that have been acquired by a compatible FDA-cleared ultrasound system. The solution identifies the thyroid lobe and proposes its margins to the user who then can make adjustments to the segmentation and approve the final result. Based on this, a lobe volume is calculated. With additional user input, thyroid nodules can be marked, quantified, and visualized as multiplanar reconstructions or 3D volume renderings. The system provides a user interface for the user to select the five ACR TI-RADS parameters and calculates the ACR TI-RADS level from the user input for each nodule. All proposed results must be verified, adjusted if necessary, and confirmed by the user before they can be added to an automatically generated clinical report.

The Infinity software runs on a stand-alone computer (Infinity Workstation – not part of the medical product) that fulfills the defined minimum requirements. It takes as an input a sequence of ultrasound images that are transmitted from the ultrasound to the Infinity Workstation

wirelessly through the Infinity Box. The Infinity Box is a piece of hardware that connects to compatible standard ultrasound systems via digital video output such as HDMI or DVI. It grabs 2D ultrasound images through a video grabber and transfers the images to the Infinity Workstation via Wi-Fi in real-time. In addition, a small Infinity Sensor must be clipped onto the ultrasound transducer using individually designed attachments. An inertial measurement unit (IMU) tracks the orientation of the transducer during the scan and sends this information to the Infinity Workstation via Bluetooth. The Infinity Workstation combines information from the Infinity Box and Sensor to generate tomographic 3D ultrasound volumes on which the above-described image analysis can be performed.

The PIUR tUS Infinity 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 Infinity 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 Infinity 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 Infinity 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 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).

### **Technological Characteristics**

The PIUR tUS Infinity 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 Infinity 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 Infinity 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 3.1-3.20:2016, 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

## Performance Data

The PIUR tUS Infinity 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 summative usability evaluation, performance validation testing and software verification and validation testing of the PIUR tUS Infinity system. The results of the usability and performance validation testing demonstrated that the PIUR tUS Infinity system provides accurate representation of key processing parameters under a range of clinically relevant parameters associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the PIUR tUS Infinity system met all design requirements and specifications.

To validate the safety and performance of the PIUR tUS Infinity System software and machine learning algorithms, PIUR conducted performance testing that consisted of two major parts:

### 1) Volume Measurement Validation

- a. Demonstrate non-inferiority of volume measurements against conventional protocol using:
  - i. Standardized (%) absolute inter-observer differences
  - ii. Lin's Concordance Correlation Coefficient
  - iii. Mean Squared Error

### 2) ACR TI-RADS Classification Validation

- a. Demonstrate non-inferiority of the PIUR tUS Infinity in ACR TI-RADS classification against conventional 2D ultrasound using Weighted Cohen's Kappa coefficient in 196 male and female patients (US, Europe & Brazil) across multiple ethnicities and using 7 ultrasound models (covering low-end, mid-range, and high-end scanners).
- b. In addition, PIUR assessed performance for individual ACR TI-RADS sub-parameters to exclude bias or distortion introduced by 3D reconstruction using a sub-set of 102 patients. Weighted Cohen's Kappa Coefficients and Limits of Agreement for ultrasound categories (total score, composition, echogenicity, shape, margin and echogenic foci) were assessed on thyroid nodules.

Electrical safety and EMC testing were conducted on the PIUR tUS Infinity. 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 Infinity 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 Infinity system satisfies all design requirements and device specifications and is substantially equivalent to the Predicate Device.

### Substantial Equivalence

In comparison with the Predicate AmCAD device (K203555), the PIUR tUS Infinity device 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 (K203555)
<b>Product Name</b>	PIUR tUS Infinity	AmCAD-UT
<b>Manufacturer</b>	PIUR Imaging GmbH	AmCad BioMed Corporation
<b>Product Code / Regulation</b>	QIH / 21CFR 892.2050	QIH / 21CFR 892.2050
<b>Indications for Use</b>	<p>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.</p> <p>PIUR tUS Infinity 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.</p> <p>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).</p>	<p>AmCAD-UT is a Windows-based computer-aided detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images, acquired from FDA-cleared ultrasound systems. The region of interest (ROI) of a user-selected thyroid nodule is defined by users or suggested by an AI contouring algorithm. After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules. The device is intended for use on ultrasound images of discrete thyroid nodules larger than 1cm, for which a biopsy recommendation is required.</p>

Description	Subject Device	Predicate Device (K203555)
<b>Functional Capability of Image Processing</b>	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. The system provides a user interface for the user to manually select sonographic characteristics of each nodule (hyperechoic foci, echogenicity, texture, margin, orientation and anechoic areas) from which an ACR TI-RADS score will be computed.	AmCAD-UT analyzes the user-defined or AI-suggested regions of interest (ROI) of a user-selected thyroid nodule for detection and quantification of sonographic characteristics (hyperechoic foci, echogenicity, texture, margin, orientation and anechoic areas). The device further provides detailed information with visualization of sonographic characteristics of thyroid nodules.
<b>Reading Paradigm</b>	Device provides quantification and visualization of sonographic characteristics based on 3D volumetric data. Results provide proposals to be reviewed and confirmed by physicians.	AmCAD-UT is to provide quantification and visualization of sonographic characteristics after physicians' initial review of the images.
<b>Output Generated by the CAD Device</b>	The device can export volumetric data, annotated screenshots and reports. Report can contain both sides of the patient and includes all relevant diagnostic information.	The image can be annotated with the detected sonographic characteristics and be recorded by the device. The software also automatically generates reports given the user preference inputs in the analysis process.
<b>Type of Film to be Processed by the CAD Device</b>	Digital ultrasound videoclip (cineloop)	Digital ultrasound image
<b>Software Design</b>	Based on computer vision, machine learning, pattern recognition and quantification method.	Based on AI, Statistical Pattern Recognition and Quantification method
<b>Ground Truth Establishment</b>	The ground truth to be established for performance studies of the device are annotated data sets labeled by medical specialists.	The ground truth to be established for performance studies of the device is the ROI labeled by a panel of specialists.
<b>Platform</b>	Windows-based	Same
<b>Operating System</b>	Standard PC or review station	Same
<b>Clinical Application</b>	Thyroid Lesions	Thyroid cancers
<b>Image Type</b>	Ultrasound volume image	Ultrasound Image

Description	Subject Device	Predicate Device (K203555)
<b>Image Format</b>	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 Infinity	DICOM3.0, Bitmap, JPEG
<b>ROI Quantification</b>	Yes	Yes
<b>Automatically Generating Report</b>	Yes	Same
<b>Performance Testing Data to Support SE Determination</b>	Results from standalone performance testing of machine learning algorithm suggested ROIs of user-selected nodules	Results from standalone performance testing of AI suggested ROI's of user-selected nodules
<b>Device Components</b>	Infinity Box Infinity Sensor Infinity Software	N/A – Predicate is a software only device (SaMD)
<b>DICOM Compliance</b>	Yes	Same
<b>Data Acquisition</b>	Acquires medical image data from DICOM compliant Ultrasound imaging devices	Same
<b>Data / Image Types</b>	Ultrasound image via DICOM format	Same

## Conclusions

The PIUR tUS Infinity system performs as intended and presents no unacceptable risks to the intended patient population. The performance testing supports the safety of the device and demonstrate that the PIUR tUS Infinity system performs as intended in the specified use conditions. The PIUR tUS Infinity system is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed Predicate AmCAD-UT Device (K203555).