TOMTEC Imaging Systems GmbH
% Mr. Marc Bergenthal
Manager Regulatory Affairs
Freisinger Strasse 9
Unterschleissheim, Bavaria 85716
GERMANY

January 6, 2022

Re: K213544
Trade/Device Name: TOMTEC-ARENA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: October 27, 2021
Received: November 8, 2021

Dear Mr. Bergenthal:

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 and Part 809); 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213544

Device Name
TOMTEC-ARENA

Indications for Use *(Describe)*
Indications for use of TOMTEC-ARENA software are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physician in the diagnosis.

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

K213544

This 510(k) summary is provided as part of the Premarket Notification in compliance with 21CFR, Part 807, Subpart E, Section 807.92.

1) SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON

Primary Contact: Marc Bergenthal
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Germany

Date prepared: October 27, 2021

2) NAME OF THE DEVICE, INCLUDING THE TRADE OR PROPRIETARY NAME IF APPLICABLE, THE COMMON OR USUAL NAME, AND THE CLASSIFICATION NAME, IF KNOWN

Common Name:	Picture archiving and communications system
Proprietary Name:	TOMTEC-ARENA
Classification Name:	21 CFR 892.2050, System, Image Processing, Radiological
Class	2
Classification Product Code:	QIH
Subsequent Product Code:	LLZ

3) INDICATIONS FOR USE

Indications for use of TOMTEC-ARENA software are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physician in the diagnosis.

4) DEVICE DESCRIPTION

TOMTEC-ARENA is a clinical software package for reviewing, quantifying and reporting digital medical data. The software can be integrated into third party platforms.

Platforms enhance the workflow by providing the database, import, export and other services. All analyzed data and images will be transferred to the platform for archiving, reporting and statistical quantification purposes.

TTA2 consists of the following optional modules:

- IMAGE-COM
- REPORTING
- AutoStrain LV / SAX / RV / LA
- 2D CPA
- FETAL 2D CPA
- 4D LV-ANALYSIS
- 4D RV-FUNCTION
- 4D CARDIO-VIEW
- 4D MV-ASSESSMENT
- 4D SONO-SCAN
- TOMTEC DATACENTER (incl. STUDY LIST, DATA MAINTENANCE, WEB REVIEW)

The purpose of this traditional 510(k) pre-market notification is to introduce semi-automated cardiac measurements based on an artificial intelligence and machine learning (AI/ML) algorithm. The AI/ML algorithm is a Convolutional Neuronal Network (CNN) developed using a Supervised Learning approach.

This AI/ML algorithm enables TOMTEC-ARENA to produce semi-automated and editable echocardiographic measurements on BMODE and DOPPLER datasets. The algorithm was developed using a controlled internal process that defines activities from the inspection of input data to the training and deployment of the algorithm:

> The training process begins with the model observing, learning, and optimizing its parameters based on the training pool data. The model's prediction and performance are then evaluated against the test pool. The test pool data is set aside at the beginning of the project.

During the training process, the AI/ML algorithm learned to predict measurements by being presented with a large number of echocardiographic data manually generated by qualified healthcare professionals.
The echocardiographic studies were randomly assigned to be either used for training (approx. 2,800 studies) or testing (approx. 500 studies).

A semi-automated measurement consists of a cascade of detection steps. It starts with a rough geometric estimate, which is subsequently refined more and more:

> The user selects a frame on which the semi-automated measurements shall be performed in TOMTEC-ARENA. Image- & metadata, e.g. pixel spacing, are transferred to the semi-automated measurement detector. The semi-automated measurement detector predicts the position of start and end caliper in the pixel coordinate system. These co-coordinates are transferred back to the CalcEngine, which converts the received data back into real world coordinates (e.g. mm) and creates the graphical overlay. This superimposed line can be edited by the user.

The end user can edit, accept, or reject the measurement(s).

This feature does not introduce any new measurements, but allows the end user to perform semi-automated measurements. The end user can also still perform manual measurements and it is not mandatory to use the semi-automated measurements. The semi-automated measurements are licensed separately.

5) SUBSTANTIALLY EQUIVALENT DEVICES

Predicate Device: TOMTEC-ARENA
K201632 (August 14, 2020)

Reference Device: EPIQ and Affiniti Series Diagnostic Ultrasound System
K211597 (September 08, 2021)

TOMTEC Imaging Systems GmbH believes that the TOMTEC-ARENA (TTA2.50) modifications that are the subject of this 510(k) are substantially equivalent to TOMTEC-ARENA (TTA2.40) (K201632).

6) TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES

The TOMTEC-ARENA software with the modified modules has the same intended use and technological characteristics as the legally marketed predicate devices. A comparison of the proposed TOMTEC-ARENA application to the currently marketed predicate device (TOMTEC-ARENA) and reference device (Philips EPIQ and Affiniti Ultrasound Systems with Auto Measure) are provided in the tables below:

GENERAL COMPARISON

Feature	Predicate Device TOMTEC-ARENA	Reference Device Philips EPIQ and Affiniti Ultrasound Systems with Auto Measure	Subject Device TOMTEC-ARENA	Discussion / Comment
K-number	K201632	K211597	Not available	Subject of this submission is TOMTEC-ARENA.
Regulation Number and Regulation Name	21 CFR 892.2050; System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	21 CRF 892.1550 Ultrasonic pulsed doppler imaging system.	21 CFR 892.2050; System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	Identical to predicate device.
Classification Product Code	LLZ	IYN	QIH	Identical to predicate device (primary and secondary product code switched).
Subsequent Product Codes	QIH	ITX, IYO, OBJ, QIH	LLZ	Identical to predicate device (primary and secondary product code switched).
Class	2	2	2	Identical to predicate and reference device.
Classification Panel	Radiology	Radiology	Radiology	Identical to predicate and reference device.
Device Name	TOMTEC-ARENA	EPIQ Series Diagnostic Ultrasound System, Affiniti Series Diagnostic Ultrasound System	TOMTEC-ARENA	Identical to predicate device.
Version	TTA2.40	VM 9.0 (Ultrasound System Software version/platform)	TTA2.50	Version of subject device changed due to new features.

Intended Use	TOMTEC-ARENA software is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities.TOMTEC-ARENA is not intended to be used for reading of mammography images.	The intended use of Philips EPIQ series diagnostic ultrasound systems is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intra-cardiac Echo, Intra-luminal, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal(Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung. The clinical environments where Philips EPIQ diagnostic ultrasound systems can be used include clinics, hospitals, and clinical point-of care for diagnosis of patients. When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.	TOMTEC-ARENA software is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities.TOMTEC-ARENA is not intended to be used for reading of mammography images.	Intended Use/ Indications for use of predicate and subject device are identical (unchanged).Intended Use/ Indications for use of reference device and subject device are similar and considered equivalent (specifically if compared for the clinical use case/ workflow of the subject feature).
Indications for Use	Indications for use of TomTec-Arena TTA2 software are quantification and reporting of cardiovascular, fetal, abdominal structures and function of patients with suspected disease to support the physician in the diagnosis		Indications for use of TOMTEC-ARENA TTA2 software are quantification and reporting of cardiovascular, fetal, abdominal structures and function of patients with suspected disease to support the physician in the diagnosis	
where used (hospital, home, ambulance, etc.)	Hospitals, clinics, and physician´s offices.	Clinics, hospitals, and clinical point-of care for diagnosis of patients.	Inside and outside of Hospitals, Clinics, and Physician´s offices.	Subject of submission; The intended use environment was revised and extended. Environmental conditions have been considered.

Design	Software as a medical device	Hardware and Software	Software as a medical device	Identical to predicate and reference device.

IMAGE-COM				
Feature	**Predicate Device TOMTEC-ARENA**	**Reference Device Philips EPIQ and Affiniti Ultrasound Systems with Auto Measure**	**Subject Device TOMTEC-ARENA**	**Discussion / Comment**
Application description	IMAGE-COM is a basic module for reviewing and measuring digital medical data. It supports routine workflows for loading, analyzing and saving medical studies, e.g. for the purpose of creating reports. IMAGE-COM is where basic measurements can be performed and the entry point for advanced analysis modules. Study related routine measurements can be imported, displayed, edited and exported to accompanying reporting systems.	Auto Measure is an optional software feature on the EPIQ/Affinity Series Diagnostic Ultrasound System that provides the end user with semi automated adult echocardiography 2D and Doppler measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG, per The American Society of Echo cardiography (ASE) recommendations	unchanged	Identical to predicate device. Similar and considered equivalent to the reference device (specifically if compared for the clinical use case/workflow of the subject feature).
SW Version	5.5.5	9.0	5.5.7	Version of module IMAGE-COM changed due to new features.

Semi-automated measurements (BMODE)	Ao Asc diam Ao Ann diam Ao STJ diam Ao SV diam IVSd LA diam systole LVIDd LVIDs LVOT diam LVPWd RVDd base (RVD1) RVDd mid (RVD2) RVLd RVOT diam lax RVOT diam prox TV Ann diam ant-post IVSd-LVIDd-LVPWd (same line)	Asc Ao Diam Ao STJ Diam Ao Sinus Diam IVSd LVIDd LVIDs LVOT Diam LVPWd RV Base RV Mid RV Length TV Annulus	unchanged	For these measurements, a measurement suggestion can now be initialized on a self-selected image within a clip. The measurement suggestion can be edited. Manual measurements as with TTA2.40.00 are still possible.Support of additional semi-automated measurements compared to reference device. Additional measurements rely on same principle/ technology (e.g. line detection, single-point) as those included in reference device.

Semi-automated measurements (DOPPLER)	MV A Vel MV E Vel MV E/A Slope (MV A Vel, MV E Vel, MV Time) MV Dec. Slope (MV Dec Time, MV E Vel) LVOT VTI AV VTI PV VTI TR Vmax LV E'(l) LV A'(l) LV E'(s) LV A'(s) RV A'(l) RV E'(l) RV S'(l)	MV Peak A Vel MV Peak E Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI LVOT Vmax AV VTI AV Vmax PV VTI PV Vmax TR Vmax Lat E' Vel Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel	unchanged	For these measurements, a measurement suggestion can now be initialized on a self-selected image within a clip. The measurement suggestion can be edited. Manual measurements as with TTA2.40.00 are still possible. Support of additional semi-automated measurements compared to reference device. Additional measurements rely on same principle/ technology (e.g. line detection, single-point) as those included in reference device. (MV Dec. Slope is calculated from MV E Vel and MV Dec Time.)

Semi-Automation Technology	As cleared	Semi-automated adult echocardiography 2D and Doppler measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements.The automation of measurements is constrained to the specific imaging mode (2D, Doppler) as recommended by ASE guidelines.	Semi-automated adult echocardiography 2D and Doppler measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements.The automation of measurements is constrained to the specific imaging mode (2D, Doppler) as recommended by ASE guidelines.	Subject of submission; Proposed feature includes optional semi-automation of existing measurements available to the end user during routine ultrasound exam similar to reference device. Semi-automated measurements quantify image data through an AI-based algorithm that was trained with a machine-learning model.Workflow improvements for user convenience.No impact to the safety or effectiveness of the device.
User Interface Presentation	As cleared	User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.	User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.	Similar to predicate and reference device. The set of available measurements are unchanged to the predicate device. Workflow improvements for user convenience. No impact to the safety or effectiveness of the device.

7) NON-CLINICAL PERFORMANCE DATA

The proposed modifications were tested in accordance with TOMTEC's internal processes. Design Control activities to assure the safe and effective performance of the modified TOMTEC-ARENA include but are not limited to the following:

- Product Specifications
- Design Review
- Risk Analysis
- Software Verification

TOMTEC-ARENA is considered a Moderate Level of Concern. Software verification was performed according to the standard IEC 62304 "Medical device software - Software life-cycle processes".

A Summative Usability Evaluation was performed considering FDA's Guidance for Industry and FDA Staff "Applying Human Factors and Usability Engineering to Medical Devices" and according to the standard IEC 62366-1 "Medical devices – Part 1: Application of usability engineering to medical devices". TOMTEC-ARENA has been found to be safe and effective for the intended users, uses, and use environments.

Completion of all verification activities demonstrated that the subject device meets all design and performance requirements. Verification activities performed confirmed that the differences in the design did not adversely affect the safety and effectiveness of the subject device.

8) SUMMARY OF CLINICAL TESTS:

No clinical testing conducted in support of substantial equivalence when compared to the predicate devices.

9) CONCLUSION

Verification and validation activities required to establish the performance, functionality, and reliability characteristics of the modified TOMTEC-ARENA software with respect to the predicate device(s) were performed successfully. Testing performed demonstrated that the proposed TOMTEC-ARENA (TTA2.50) meets defined requirements and performance claims.

Based on the conformance to standards, development under TOMTEC's Quality Management System, and the successful verification and validation testing, TOMTEC believes that the proposed TOMTEC-ARENA (TTA2.50) is substantially equivalent to the legally marketed predicate device(s).