TOMTEC Imaging Systems GmbH
% Mr. Marc Bergenthal
Manager Regulatory Affairs
Edisonstrasse 6
Unterschleissheim, Bavaria 85716
GERMANY

August 14, 2020

Re: K201632
Trade/Device Name: TOMTEC-ARENA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 12, 2020
Received: June 16, 2020

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); 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201632

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 physicians 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

K201632

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

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Germany

Date prepared: June 12, 2020

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

Product code: QIH, Class II

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 physicians in the diagnosis.

4) DEVICE DESCRIPTION

TOMTEC-ARENA (TTA2) is a clinical software package for reviewing, quantifying and reporting digital medical data. The software is compatible with different IMAGE-ARENA platforms and 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:

- TOMTEC-ARENA SERVER & CLIENT
- IMAGE-COM/ECHO-COM
- REPORTING
- AutoStrain (LV, LA, RV)
- 2D CARDIAC-PERFORMANCE ANALYSIS (Adult and Fetal)
- 4D LV-ANALYSIS
- 4D RV-FUNCTION
- 4D CARDIO-VIEW
- 4D MV-ASSESSMENT
- 4D SONO-SCAN

5) SUBSTANTIALLY EQUIVALENT DEVICES

Primary Predicate Device: TomTec-Arena TTA2
K150122 (February 13, 2015)

Secondary Predicate Device: QLAB Advanced Quantification Software
K200974 (June 03, 2020)

TOMTEC Imaging Systems GmbH believes that the TOMTEC-ARENA modifications that are the subject of this 510(k) are substantially equivalent to TomTec-Arena TTA2 (K150122).

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 primary predicate device (TomTec-Arena TTA2) and secondary predicate device (QLAB Advanced Quantification Software) are provided in the tables below:

Feature	Primary Predicate Device TomTec-Arena (K150122)	Secondary Predicate Device QLAB (K200974)	Subject Device TOMTEC-ARENEA	Discussion / Comment
GENERAL COMPARISON				
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.	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	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 of primary and subject device are identical (unchanged)Intended Use/Indications for use of secondary predicate and subject device are comparable and considered equivalent.
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 physicians in the diagnosis	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	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 physicians in the diagnosis	Indications for use of primary and subject device are identical (unchanged). Intended Use/Indications for use of secondary predicate and subject device are comparable and considered equivalent.
Anatomical Site	Quantification and reporting of cardiovascular, fetal, and abdominal structures and function.	Quantification of imaging data acquired from ultrasound machines of various anatomical structures and function.	Quantification and reporting of cardiovascular, fetal, and abdominal structures and function.	Identical to primary and secondary predicate.
where used (hospital, home, ambulance, etc.)	Hospitals, clinics, and physician´s offices.	Hospitals, clinics, and physician´s offices.	Hospitals, clinics, and physician´s offices.	Identical to primary and secondary predicate.
Design	Software as a medical device	Software as a medical device	Software as a medical device	Identical to primary and secondary predicate.
4D RV-FUNCTION				
Application Description	4D RV-Function provides a comprehensive evaluation of the right ventricle including volumes and strain analysis. It provides EDV, ESV, RVEF, SV, RVLS, TAPSE and FAC. Distance measurements can also be analyzed. This software delivers a quick and reproducible analysis of the right ventricle, thus	The 3D Auto RV Q-App is an integration of the segmentation engine of the QLAB HeartModel and the TOMTEC-ARENA 4D RV-Function thereby providing a dynamic Right Ventricle clinical functionality.	The 4D RV-Function is a right ventricular quantification tool for routine clinical work, pulmonary hypertension, and right-sided heart failure. The application helps to overcome complexity of right-ventricle analysis by calculating standard values based on a semi-	Revised for clarity. Considered equivalent to primary predicate. No impact to the safety or effectiveness of the device. Comparable and considered equivalent to secondary predicate. This modification to QLAB was cleared by K191647.

	increasing your diagnostic confidence by visualizing the complexity of the RV shape in 3D.		automatically generated 3D surface model.	
SW Version	2.0	15.0	3.0	Updated due to changes to SW code. Integrates HeartModel auto-segmentation technology with 4D RV-Function algorithm for RV border placement.
Measurements	Volume and function of Right Ventricle	EDVI ESVI	Added: EDVI ESVI	Added measurements are identical to secondary predicate device.
Export Formats:	As cleared	Beutel value export into .stl and .obj format	Added: Beutel value export into .stl and .obj format	Identical to secondary predicate. Workflow improvements for user convenience. No impact to the safety or effectiveness of the device.
Contour Generation	3D surface model is created based on user defined anatomical landmarks. User is able to edit the contour of the surface model.	3D surface model is created automatically using machine learning algorithms without user interaction. User is able to edit, accept or reject the contours or the anatomical landmarks.	3D surface model is created automatically using machine learning algorithms without user interaction. User is able to edit, accept or reject the contours or the anatomical landmarks.	Identical to secondary predicate. Workflow improvements for user convenience. No impact to the safety or effectiveness of the device.
4D MV-ASSESSMENT				
Application Description	4D MV-Assessment is used for comprehensive morphological and functional assessment of the mitral valve. Based on an easy and intuitive workflow the application package generates models of anatomical structures such as MV annulus, leaflet and the closure line. Automatically derived parameters allow quantification of pre- and post-operative valvular function and comparison of morphology. 4D MV-Assessment improves the presentation of anatomy and findings and visualizes the complex morphology and dynamics of the mitral valve.	The 3D Auto MV Q-App is a semi-automatic tool that essentially is an integration of the machine-learning derived segmentation engine of the QLAB HeartModel and the TOMTEC-Arena TTA2 4D MV-Assessment application thereby providing a dynamic Mitral Valve clinical quantification tool.	4D MV-ASSESSMENT provides a morphological and functional analysis of the mitral valve (MV) using 3D/4D echocardiography data. Models of anatomical structures such as MV annulus, leaflets and the closure line are generated. The derived parameters allow quantification of pre- and post-operative valvular function and a comparison of morphology.	Revised for clarity. Considered equivalent to primary predicate. No impact to the safety or effectiveness of the device. Comparable and considered equivalent to secondary predicate. This modification to QLAB was cleared by K200974-
SW Version	2.3	15.0	2.5	Updated due to changes to SW code.

Measurements	As cleared	Prolapse Height Open Coaptation Gap Open Coaptation Width Open Coaptation Area 3D C-shaped Annulus Distal Anterior Leaflet Angle	Added: Prolapse Height Open Coaptation Gap Open Coaptation Width Open Coaptation Area 3D C-shaped Annulus Distal Anterior Leaflet Angle	Identical to secondary predicate.
Contour Generation	3D surface model is created based on user defined anatomical landmarks. User is able to edit the contour of the surface model before proceeding with the workflow.	3D surface model is created semi-automatically using machine learning algorithm without user interaction. User is able to edit, accept, or reject the initial landmark proposals of the mitral valve anatomical locations.	3D surface model is created semi-automatically using machine learning algorithm without user interaction. User is able to edit, accept, or reject the initial landmark proposals of the mitral valve anatomical locations.	Identical to secondary predicate. Workflow improvements for user convenience in initial model display and landmark proposal. User is still able to edit, accept or reject the contours. No impact to the safety or effectiveness of the device.
4D LV-ANALYSIS				
Application Description	Volume quantification and function analysis of the left ventricle based on 3D data has proven to be more accurate and reproducible than using 2D clips. 4D LV-Analysis is a vendor independent offline solution for 3D speckle tracking. It provides an automated workflow for quantitative and reproducible analysis of left ventricular deformation and global strain values. 4D LV Function is a basic application for the assessment of left ventricular volumes, EF and GLS while 4D LV Analysis allows for advanced investigations including twist, regional strain and deformation analysis. Results are mapped onto the LV Beutel surface for clear visualization. All results can be stored and exported.	The Dynamic HeartModel (DHM) provides automatic 3D anatomical borders and left ventricle (LV) and left atrium (LA) border tracking across all frames of the cardiac cycle or cycles.	4D LV-ANALYSIS provides morphological and functional analyses of the left ventricle. Based on 3D echo datasets a 4D model (Beutel) is generated that represents the cavity of the LV and optionally also the LA. Volumes, Strain and Displacement are quantified on a global and segmental level.	Revised for clarity. Considered equivalent to primary predicate. No impact to the safety or effectiveness of the device. Comparable and considered equivalent to secondary predicate.
SW Version	3.1	15.0	3.2	Updated due to changes to SW code.

Measurements	As cleared	LAVmin LAVmax LA EF	Added: LA EDV (LA EDVI) LA ESV (LA ESVI) LA PreAV (LA PreAVI) LA trueEF LA EF LA GLS	Same technology extended to Atrium (LA Option in 4D LV-Analysis). LA EDV corresponds to LAVmin, and LA ESV corresponds to LAVmax. LA PreAV is based on the same dynamic quantification as LA volume curve (prior to contraction). LA trueEF uses the same formula as LA EF but different volume values (LA PreAV instead of LAVmax). LA GLS is a well-known parameter and described in clinical literature.
Export formats:	As cleared	Beutel value export into .stl and .obj format	Added: Beutel value export into .stl and .obj format	Identical to secondary predicate (see "4D RV-Function").
Enhancements:	As cleared	n/a	Adapted Bullseye based an ASE2015 guideline. Workflow improvements by removed Beutel revision step & contour proposal and retracking within tracking revision step.	Workflow improvements for user convenience. No impact to the safety or effectiveness of the device.
AUTOSTRAIN				
Application Description	n/a - features and functionality were part of IMAGE-COM (AutoSTRAIN Addins) and 2D CPA	AutoStrain LV, LA, RV included	AutoStrain is a quantification tool of global and regional function based on contour detection and tracking. It supports a bull's eye display of Time to Peak Longitudinal Strain and End-Systolic Longitudinal Strain. Further, this CAP provides the calculation of GLS (Global Peak Longitudinal Strain).	Based on cleared Addins of IMAGE-COM and 2D CPA, a dedicated module (CAP) was released. This CAP only includes features and measurements that were already available in IMAGE-COM (and respective Addins), 2D CPA or have been cleared by QLAB. The integration "on cart" requires dedicated CAPs (e.g. for the application layout). This CAP is used in the same clinical context and workflows. No impact to the safety or effectiveness of the device.
SW Version	n/a - features and functionality were part of IMAGE-COM (AutoSTRAIN Addins) and 2D CPA	15.0	2.1	No previous SW version as features and functionality were included in IMAGE-COM and/or 2D CPA

Measurements	n/a - features and functionality were part of IMAGE-COM (AutoSTRAIN Addins) and 2D CPA	LASr ED LAScd ED LASct ED LASr AC LAScd AC LASct AC	Added: LASr ED LAScd ED LASct ED LASr AC LAScd AC LASct AC	Measurements available within this CAP were already available in IMAGE-COM/2D CPA or are identical to the secondary predicate (QLAB). No impact to the safety or effectiveness of the device.

Feature	**Primary Predicate Device** **TomTec-Arena** **(**K150122**)**	**Subject Device** **TOMTEC-ARENEA**	**Discussion / Comment**
IMAGE-COM			
Application description	Image-Com is a dedicated DICOM viewer for cardiovascular ultrasound and Cath Lab examinations. Easy and quick image review is supported by a variety of time saving features. Prior studies can easily be compared with current examinations and the simultaneous display of Cath Lab, echo or nuclear medicine examinations provides additional clinical information.	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.	Revised for clarity. Considered equivalent to primary predicate. No impact to the safety or effectiveness of the device.
SW Version	5.4	5.5	Updated due to changes to SW code.
Measurements	ECHO	Added: Annulus dmin Annulus dmax Annulus dmean Annulus Area Annulus Perimeter Annulus d(area) Ann-Ost left diam Ann-Ost right diam MV E Valsalva MV A Valsalva MV E/A Valsalva	Existing ECHO measurements have been extended. No impact to the safety or effectiveness of the device.
Measurements (continued)	Vascular	Renal (AT & AI)	Existing Vascular measurements have been extended. No impact to the safety or effectiveness of the device.

Exam Types	ECHO and Vascular	Added: Pediatric Cath	ECHO and Vascular were extended to Pediatric. Extension of existing measurement methods to Cath.
Deployment	Application based (FAT)	Browser support added	IMAGE-COM is available as a zero footprint solution (TOMTEC ZERO). No change in intended use or use environment. No impact to the safety or effectiveness of the device.
Auto LV	AutoLV enables IMAGE-COM to quantify left ventricular function based on 4-chamber and 2-chamber views of the left ventricle (biplane Simpson) with a single mouse click per view	Unchanged	Identical to primary predicate.
Auto Strain	The AutoStrain application yields cardiac function analysis based on a workflow. After selecting views to analyze, and starting the application results are shown directly for user's review.	Unchanged	Identical to primary predicate.
AutoSTRAIN Measurements (continued)	As cleared	Added: LVLd (A4C) LVLs (A4C) LVLd (A2C) LVLs (A2C) AVC	Length measurements/values added because of user needs: User is able to double check if LV axis is acquired without foreshortening. In this case both Diastolic and Systolic Major Axis should be similar.
AutoSTRAIN Enhancements	Bullseye (16 segments)	Bullseye (18 segments)	Adapted Bullseye based on ASE2015 guideline.
Auto LA	AutoLA* is a fast and intuitive automation of Simpson's biplane method. By selecting apical 4- and 2-chamber views, AutoLA finds end-systole and proposes tracings of the left atrial blood tissue interface	Unchanged	Identical to primary predicate.
Auto LA Measurements	LA Vol (Simpson)	Extension of existing left atrium LA volume (Simpson) measurements with contour proposal step	Improvement for user convenience. No impact to the safety or effectiveness of the device.
Cath-QCA	Cath QCA is a calculation of stenosis diameter and area, obstruction and reference diameters and obstruction length	Unchanged	Identical to primary predicate.
Cath-QVLA Measurements	Cath-QVLA is a calculation of EDV and ESV, EF, SV, CO of the Left ventricle	Unchanged	Identical to primary predicate.
4D CARDIO-VIEW			
Application Description	4D Cardio-View is a vendor independent offline solution to review and analyze 3D echo data. It offers an easy and fast navigation to get the perfect 3D view with just two clicks by using the unique	4D CARDIO-VIEW is an advanced analysis tool for 3D/4D echocardiography data. Anatomical structure visualization, volume measurements (LV and/or generic), and specified or manual	Revised for clarity. Considered equivalent to primary predicate. No impact to the safety or effectiveness of the device.

	D'Art tool. Features like the multi-slice D'Art (multiple 2D slices), basic measurements and workflow based volume measurements make 4D Cardio-View an all-purpose solution for any cardiac structure. All measurements and views can be stored as bookmarks for easy retrieval at any time.	measurements are possible. Various tools are available for rendering that display 2- and 3-dimensional morphology and function for defined structures.	
SW Version	3.0	3.1	Updated due to changes to SW code.
Measurements	as cleared	Unchanged	Identical to primary predicate.
Export formats:	as cleared	Added: Beutel value export into .stl and .obj format	Identical to secondary predicate (see "4D RV-Function").
2D CARDIAC-PERFORMANCE ANALYSIS (Adult and Fetal)			
Application Description	2D Cardiac Performance Analysis is a vendor independent offline solution for the quantification of left ventricular deformation. Detailed analysis of myocardial velocity, displacement, strain and strain rate is performed based on 2D speckle tracking in long or short axis views. Basic parameter assessment and comprehensive result export options make 2D CPA suitable for research and routine use.	2D CARDIAC PERFORMANCE ANALYSIS (2D CPA) provides parameters for myocardial function and deformation analysis. Based on two dimensional echo B-Mode datasets a speckle tracking algorithm supports the calculation of 2D-contour models of the endocardial and epicardial border. Corresponding velocities, displacements, strains, strain rates and functional parameters can be derived. The results are displayed as figures, in charts or they are available as numerical values.	Revised for clarity. Considered equivalent to primary predicate. No impact to the safety or effectiveness of the device.
		FETAL 2D CARDIAC PERFORMANCE ANALYSIS (FETAL 2D CPA) is a vendor independent, offline solution for the quantification of cardiac deformation of the fetal heart. Detailed analysis of myocardial velocity, displacement, strain and strain rate is performed based on 2D speckle tracking in the long axis views of the left ventricle and right ventricle. Basic parameter assessment as well as advanced quantifications, together with comprehensive result export options, make FETAL 2D CPA suitable for research and routine use.	Analysis of the fetal heart can be performed based on the cleared implementation of speckle tracking that is available in 2D CPA. Quantification of fetal structures is part of the cleared Indications for Use. Technology already available is applied within the Intended Use/Indications for Use of the device. Substantial evidence for this modification is available. Optimized workflow (exclusively for 4CH clips) to analyze both ventricles in the same 4CH clip and within the same application session. Same algorithm for contour detection is used.
SW Version	1.2	1.4	Updated due to changes to SW code.

Measurements	Left ventricle strain calculation	Extended to right ventricle strain and atrium strain (e.g. GLS and segmental strain/strain rate values). - MAPSE (lateral and septal) - Basal ventricle diameter at ES and ED of RV and LV - Ventricle length at ES and ED of RV and LV - Myocardial area at ED of LV and RV	Existing measurements were extended to right ventricle strain and atrium strain (similar to LA Option).
REPORTING			
Application Description	Dedicated module for Ultrasound Reporting.	REPORTING provides various workspaces which are dedicated to different clinical applications and supports the workflow within clinical institutions. Measurements can be imported, modified and exported in order to support connected reporting systems.	Revised for clarity. Considered equivalent to primary predicate. No impact to the safety or effectiveness of the device.
SW Version	2.01	2.40	SW version is identical and correspond to the TOMTEC-ARENA version, due to release dependencies.
Workspaces / Areas	Echo	Added: Vascular Stress Echo Pediatric Fetal TEE Pre/Post OP	Based on existing and extended measurements, new workspaces were added in order to display and structure those measurements in a dedicated workspace (view) for easy clinical reporting. 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 (TTA2.40) 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 (TTA2.40) is substantially equivalent to the legally marketed predicate device(s).