January 11, 2022

Quipu S.R.L
% Dallas Thomas
Principal Medical Device Regulatory Consultant
Thomas Regulatory Resolutions, Inc.
5613 Tiger Way
Winter Garden, Florida 34787

Re: K202094
Trade/Device Name: Cardiovascular Suite 4.2.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 27, 2021
Received: December 29, 2021

Dear Dallas Thomas:

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,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202094

Device Name
Cardiovascular Suite 4.2.1

Indications for Use *(Describe)*
The Cardiovascular Suite 4.2.1 is a software program that is intended to aid trained healthcare practitioners in the quantitative analysis of vascular ultrasound images in adults, particularly for the measurement of the diameter and its changes on the brachial artery, the diameter and its changes on the carotid artery, the Carotid Intima-Media Thickness, and for carotid plaque analysis.

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

5.1 General Information

Preparation Date: 11 January 2022

Primary Submission Contact

Dallas L. Thomas, RAC, MHA, MPA, SSYB

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5.2 Regulatory Information

Subject Device Name	Cardiovascular Suite 4.2.1
Classification Names	Computer, Diagnostic, Programmable
Device Classification	II
Common Name	Cardiovascular Suite 4.2.1
FDA Product Code	DQK
CFR References	870.1425
Review Panel	Cardiovascular

5.3 Identification of Predicate Device

Quipu regards the Cardiovascular Suite to be substantially equivalent to the predicate K033266, which is the "Vascular Tools 5" consisting of modules: "Brachial Analyzers5", "Carotid Analyzer 5", as commercialized by Medical Imaging Applications LLC. Additionally we are including the reference devices as follows for further consideration for substantial equivalence: Reference Device: M'Ath Std K040686 by Intelligence in Medical Technologies and Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH

5.4 Subject Device Description

The Cardiovascular Suite 4.2.1 is a software indicated for estimating early cardiovascular parameters by identifying and tracking the edges of the arteries by analyzing sequences of ultrasound images or single images of the longitudinal section of the vessel.

The software consists of two main functional measurement modules:

1) the FMD-Studio for measuring Flow-Mediated-Dilation (FMD) of the brachial artery, by processing sequences of ultrasound image

2) The Carotid-Studio for measuring, by processing sequences of ultrasound images, the thickness of the carotid intima-media and the instantaneous carotid diameter that, associated with a pressure estimate, can provide arterial elasticity parameters. On single images, the software also provides a tool for Plaque Measurement and Quantification.

The system is able to process previously recorded video files or directly process the video output of an ultrasound system in real time.

The software is to be used only by trained healthcare professionals, such as laboratory technicians, nurses, doctors and/or ultrasonographers.

The use of the system for analyzing people with a distorted anatomy of the examined arterial tract is not recommended.

5.5 Indications for Use

Per the current proposed product labeling, the indications for use for the Cardiovascular Suite 4.2.1 are quoted as follows:

Indications for Use
The Cardiovascular Suite 4.2.1 is a software program that is intended to aid trained healthcare practitioners in the quantitative analysis of vascular ultrasound images in adults, particularly for the measurement of the diameter and its changes on the brachial artery, the diameter and its changes on the carotid artery, the Carotid Intima-Media Thickness, and for carotid plaque analysis.

Contraindications
The Cardiovascular Suite 4.2.1 device is not intended for use as a test that provides a direct diagnosis of any cardiovascular disease. It is intended to supplement, not substitute, the physician's decision-making process for diagnosis and treatment. It should be used in conjunction with knowledge of the patient's history and other clinical findings. It is not intended for use in pediatric population.

Please note that the above indication is slightly reworded compared to the already cleared indications for the predicate Vascular Tools 5 and updated accordingly per current FDA Guidance. The indications for use statement also provides further clarification that is complementary to the cleared predicate indications for use.

5.6 Substantial Equivalence Discussion

Any modifications between the predicate device and the subject device are provided in while the table below. The review of the indications for use and comparison characteristics provided in Error! Reference source not found. demonstrate that Cardiovascular Suite 4.2.1 is substantially equivalent to the predicate device, Vascular Tools 5. A reference device was also included.

Table 1. Substantial Equivalence Discussion

Please note a number of published article references are provided in this table.

Item No.	**Device Characteristic.**	**Proposed Device Cardiovascular Suite**	**Primary Predicate Device Vascular Tools 5**	**Reference Device: M'Ath Std.**	**Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	**Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.**
1	510 (k) Number	K202094	K033266	K040686	K090461	N/A	Difference in 510k numbers do not impact safety or efficacy of the product.
2	Device Name, Model	Cardiovascular Suite	Vascular Tools 5	M'Ath® Std	IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0	N/A	Difference in Names do not impact safety or efficacy of the product.

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3	Manufacturer	QUIPU SRL	MEDICAL IMAGING APPLICATIONS LLC	Intelligence in Medical Technologies	TOMTEC IMAGING SYSTEMS, GMBH	N/A	Differences do not impact safety or efficacy.
4	CFR Reference	870.1425	870.1425	CFR 892.2050	892.2050	N/A	Differences do not impact safety or efficacy.
5	FDA Review Panel	Cardiovascular	Cardiovascular	Radiology	Radiology	N/A	Differences do not impact safety or efficacy.
6	FDA Device Name	Computer, Diagnostic, Programmable	Programmable diagnostic computer	System, Image processing, Radiological	Ultrasonic pulsed doppler imaging system	N/A	Differences do not impact safety or efficacy.
7	FDA Product Code	DQK	DQK	LLZ	LLZ, DQK	N/A	Differences do not impact safety or efficacy.
8	Class	II	II	II	II	Identical	N/A

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9	Indications for use	The Cardiovascular Suite is a software program for the quantitative analysis of vascular ultrasound images, particularly for the measurement of the diameter and its changes on the brachial artery, the diameter and its changes on the carotid artery, the Carotid Intima-Media Thickness, and for carotid plaque analysis	Vascular Tools 5" software program has been developed to aid in quantitative analysis of longitudinal vascular ultrasound images, particularly to determine vascular diameter and intima-media thickness, as well as their changes as depicted in brachial and carotid arterial ultrasound images.	M'Ath Std software is a Windows-based application program running on a personal computer that is intended to aid the physician in the organization of patient data relating to the ultrasound images or video acquired during echo-cardiology exams of the cardiovascular system, including the patient's	The Image-Arena Platform Software is intended to serve as a data management platform for clinical application packages. It provides information that is used for clinical diagnosis purposes. The software is suited for stand-alone workstations as well as for networked multisystem installations and therefore is an image management system for research and routine use in both physician practices and hospitals. It is intended as a general purpose digital medical image processing	Substantially Equivalent	Differences do not impact safety or efficacy.

Item No.	Device Characteristic.	Proposed Device Cardiovascular Suite	Primary Predicate Device Vascular Tools 5	Reference Device: M'Ath Std.	Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH	Comparison Analysis: *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.
				characteristics. Additionally, the software allows the physician to make measurements to determine the intima-media thickness of the carotid artery from the acquired images and stores them with the patient file.	tool for cardiology. As the Image-Arena Applications software tool package is modular structured, clinical applications packages with different indications for use can be connected. Echo-Com software is intended to serve as a versatile solution for Stress Echo examinations in patients who may not be receiving enough blood or oxygen because of blocked arteries. Image-Corn software is intended for reviewing, measuring and reporting of DICOM dBta of thi batdiab rodadlities-		

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					US and XA. -It can be' driven by Image;Arena or other third party platforms and is intended to launch other clinical applications. The clinical application package 2D Cardiac Performance Analysis is indicated for cardiac quantification based on echocardiographic data. It provides measurements of myocardial function (displacement, velocity and strain) that is used for clinical diagnosis purposes of patients with suspected heart disease.		

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10	Anatomical structure of use	Carotid and brachial artery	Same	Cardio vascular bed	Cardiovascular Bed	Identical to Predicate	N/A - Cardiovascular Suite analyzes carotid and brachial artery. These sites are included in the predicate's anatomical structure of use.
11	Cardiovascular Plaque Measurement function included	Yes	No	Yes	No	Identical to Reference Device	N/A-Cardiovascular Suite' tool for carotid plaque includes geometrical and density measurements substantially equivalent to those of the reference device
12	Flow-Mediated Dilatation (FMD) function included	Yes	Yes	No	No	Identical to Predicate	N/A
13	IMT - Intima Media Thickness	Yes	Yes	Yes	Yes	Identical to Predicate and Reference Devices	N/A

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	function included						
14	Hardware requirements	Laptop or PC running Mac OS X, Microsoft Windows Operating System (OS)	Laptop or PC running Microsoft Windows Operating System (OS)	Microsoft Windows operating system	Microsoft Windows operating system on a laptop or PC	Modified	Differences do not impact safety or efficacy. Cardiovascular Suite can be used on Laptop or PC running Microsoft Windows Operating System (OS) as the predicate. Cardiovascular Suite can be used also on Mac OS X, which presents performances comparable to the Microsoft Windows Operating System and is considered one of the most robust and user friendly operating system available on the market. Therefore, this addition with respect to the predicate device, does not result in differences in the performance and safety of the device.

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15	On-line / off-line operation	On-line and off-line.	Same	Not Publicly Available	Offline Only	Identical to Predicate	N/A
16	Supported data formats	Cardiovascular Suite works on A) Video formats: DICOM, AVI, MP4, MOV B)Image formats: DICOM, PNG, JPG, BMP, TIF . These data formats are similar to those of predicate and reference devices.	DICOM, AVI, TIF, CRI, JPEG, BMP, RAW.	AVI, JPEG, GIF, TIFF, BMP, PCX, PCD, TGA, EPS, IMG, DICOM	DICOM	Modified	Differences in supported data formats do not impact safety or efficacy.
17	Calibration	Mandatory, manually performed	Same	manually performed and automatically DICOM	Not Publicly Available	Identical to Predicate	N/A- Calibration is mandatory for all the systems
18	Information for operator in case of	Warning popups and included in instructions for use.	Same	Not Publicly Available	Not Publicly Available	Identical to Predicate	Differences do not impact safety or efficacy.

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	inappropriate use						
19	Patient/ data storage	Yes: Data archive available	Same	Same	same	Identical to Predicate and Reference Device	N/A-Patients data and images are stored into the archive of the software
20	Data export	Reporting in Microsoft Excel ,RTF, RTFd, PDF, TAB Separated Values, Comma Separated Values, HTML format.	Reporting in Microsoft Excel or SAS format.	DICOM and pdf format	Data can be exported in PDF format.	Modified	Differences do not impact safety or efficacy. Cardiovascular Suite reporting in Microsoft Excel , PDF, TAB Separated Values, Comma Separated Values. The additional format with respect to the predicate/references can be read by the same software program (Microsoft Excel and SAS). Moreover, the software architecture and more specifically the data export module, has been tested and validated according to IEC 62304

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							and taking into consideration risk analysis and reduction. Therefore, this addition with respect to the predicate device, does not result in differences in the performance and safety of the device.
21	Modules	Two: one for FMD analysis and the other for Carotid analysis	Same	Not Publicly Available	Multiple Modules based on Publicly Available data from 510k Summary.	Identical to Predicate and Reference Device	N/A-Two modules both for Cardiovascular Suite and the predicate device.
22	Multi-user Functionality	Yes: protected user access by password to the software	No	Not Publicly Available	Yes, multi user functionality included.	Substantially Equivalent to Reference device.	N/A- Comment: Cardiovascular Suite provides a protected user access by password to the software. This feature has been introduced to guarantee safety in data access. Moreover, the multi-user access of the software has been tested and validated according to IEC 62304 and taking into consideration risk

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							analysis and reduction. Therefore, this addition with respect to the predicate device, does not result in differences in the performance and safety of the device.
23	Licensing Issuance	Dongle Licensekey and web based	Web based	LICENSE KEY	Not Publicly Available	Substantially Equivalent to attributes of both Predicate & Reference Devices	The systems provide a licensing approach web-based. In addition, Cardiovascular Suite can provide license to the customer by dongle-key use. Dongle form is tightly controlled licensing. Moreover, the licensing process of the software has been tested and validated and it is further verified during the production procedure. Therefore, this addition with respect to the predicate device, does not result in differences in the performance and safety of the device.

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24	FMD Input image modality	Ultrasound image sequences in B-mode modality; Ultrasound image sequences in Duplex mode (simultaneous acquisition of B-mode and Doppler)	Ultrasound image sequences in B-mode modality; Doppler Flow Analysis not supported	B-mode and color flow	Not Included	Substantially Equivalent to Predicate	Differences do not impact safety or efficacy. Cardiovascular Suite supports B-mode as the predicate and reference device. In addition Doppler flow analysis is also supported part of the predicate device.
25	Measured /computed parameters	Flow Mediated Dilation (FMD). Shear rate detection	Flow Mediated Dilation (FMD)	Not Publicly Available	Not Publicly Available	Modified	Both devices provide instantaneous brachial diameter that can be used to evaluate Flow-Mediated-Dilation. In addition, FMD Studio, thanks to the Doppler Flow Analysis can provide Shear rate estimation, which is not expected to result in differences in safety and efficacy.
26	Exam type	Measurement performed on B-mode longitudinal section of the artery, which is imaged	Same	Not Publicly Available	Not Publicly Available, however based on the product website they do include multiple	Identical to predicate	N/A- Measurement performed on B-mode longitudinal section of the artery, which is imaged above the

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		above the antecubital fossa in the longitudinal plane			measurement functionalities.		antecubital fossa in the longitudinal plane
27	Detection algorithm / other algorithms	Contour tracking algorithm based on edge detection operator.	Globally optimal graph search border detection approach	Not Publicly Available	Not Publicly Available	Modified	Differences do not impact safety or efficacy. Contour tracking approach. Both devices include an algorithm for the automatic detection of the border of the vessel, which is used for the computation of the vessel diameter. The brachial analysis module of Vascular Tools 5 performs an automatic detection of the edges of the vessel using a globally optimal graph search border detection approach. [REF] The operator draws a region of interest (ROI) in which the best definition of the edges of the vessel is detectable on the first frame of the individual frame sequences or

Item No.	Device Characteristic.	Proposed Device Cardiovascular Suite	Primary Predicate Device Vascular Tools 5	Reference Device: M'Ath Std.	Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH	Comparison Analysis: *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.
							movie clips. The analysis proceeds automatically in supervision mode thus allowing the operator to exclude from the analysis poor-quality frames or frames in which the edges of the vessel are not correctly detected. Similarly, using FMD Studio, the approximate position of the edges of the vessel is manually located before starting the examination. After this procedure, an automatic contour tracking algorithm, based on a mathematical edge detector operator (first order absolute central moment [REF]), locates and tracks the edges, supplying information about quality and time course of measurements in real time. On completion of the analysis, both methods automatically generate a report, with all the

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							recorded measurements. The results obtained using the two systems have been evaluated in a comparison study [Faita et Al, REF] performed on 60 participants, which showed an excellent level of agreement in vessel edge location and subsequent diameter evaluation. Therefore the difference in the detection algorithm does not result in differences in the performance and safety of the device.
28	ECG gating	Not required	Not required	Not Publicly Available	Not Included	Identical to predicate	N/A
29	Output (displayed / stored data and results)	Instantaneous diameter chart Mean diameter chart Time averaged positive Shear Rate Chart time averaged positive shear	1 – Instantaneous diameter chart 2 – Third order polynomial fit chart 3 – EKG gated	Not Publicly Available	Not Publicly Available, but they do include multiple data formats based on product details.	Modified	Differences in output displays of stored data and results, do not impact safety or efficacy.

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		rate time averaged negative shear rate Mean diameter D Baseline [mm]: value of the baseline diameter D Maximum [mm]: value of the maximum diameter during vasodilation D Recovery [mm]: diameter value in the recovery phase after vasodilation MD [%]: Flow Mediated Dilation FMDr [%]: Flow Mediated Dilation calculated in relation to the diameter in the recovery phase after vasodilation SR Maximum [s-	Doppler flow Doppler Waveform envelop detection: 1 measure per frame – Flow Integral AUC on Cycle 1 measure per frame – Flow Maximum in Cycle 1 measure per frame - Flow Average in Cycle				

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		1]:maximum value of the shear rate SR Baseline[s-1]:maximum value of the shear rate SR Area [dimensionless]: area under the curve of the shear rate, Time Average Wall Shear Rate (computed using Doppler flow velocity waveform) GTN [%]: GTN Induced Dilation					
30	Report review	Yes	Yes	Not Publicly Available	Yes report review in PDF is available.	Identical to Predicate and a reference device.	N/A
31	**CAROTID** Input data modality	Ultrasound B-mode image sequences	Ultrasound B-mode image sequences	Not Publicly Available	Ultrasound B-mode image sequences	Identical to predicate and a reference device.	N/A - Cardiovascular Suite supports B-mode as the predicate does

Item No.	Device Characteristic.	Proposed Device Cardiovascular Suite	Primary Predicate Device Vascular Tools 5	Reference Device: M'Ath Std.	Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH	Comparison Analysis: *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.
32	Measurement type / Output	Intima media thickness (IMT), diameter and elasticity of carotid arteries: mean and maximum IMT reported for each frame diameter and IMT measurement in image sequences mean distension, cross-sectional compliance coefficient, cross-sectional distensibility coefficient, Stiffness, Young module Doppler Flow Velocity	Intima media thickness (IMT) and diameter of carotid arteries: mean and maximum IMT reported for each frame diameter and IMT measurement in image sequences.	IMT, Plaque (geometric and statistics))and elasticity parameters	IMT and Diameter of Carotid Arteries. Additional measurements are also available based on the product website. Also included the doppler Flow Velocity.	Modified between predicate and reference devices.	Differences do not impact safety or efficacy. WITH RESPECT TO THE PREDICATE: The predicate and reference devices evaluate diameter and IMT, starting from a region of interest defined by the operator, in B-mode image sequences. In addition diameter data from Carotid Studio, when combined with an estimate of pressure, obtained through legally marketed devices, provide parameters of arterial elasticity. Carotid intima-media thickness (IMT) and diameter elasticity are markers of structural and functional vessel wall properties. Both parameters have been found in population-based studies to be associated with cardiovascular risk factors and prevalent cardiovascular

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							disease. The estimation of carotid elasticity by Carotid Studio has been implemented by adopting equations and modalities suggested by opinion leaders guidelines . Cardiovascular Suite measurement methods have been validated in terms of accuracy and reproducibility . Cardiovascular Suite usability requirements are defined to avoid confusion in results visualization, highlighting IMT and clearly identifying all the parameters. Finally, it should be mentioned that the Cardiovascular Suite device is intended to supplement, not substitute, the physician's decision-making process; it should be used in conjunction with knowledge of the patient's history and other clinical findings.

Item No.	**Device Characteristic.**	**Proposed Device Cardiovascular Suite**	**Primary Predicate Device Vascular Tools 5**	**Reference Device: M'Ath Std.**	**Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	**Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.**
							As a conclusion, this technological characteristic does change the safety or effectiveness of the device. WITH RESPECT TO THE REFERENCE Device M'Ath: both systems evaluate arterial elasticity (distensibility) by contour tracking algorithm and provide a tool for plaque analysis based on similar approaches.
33	Exam type	Measurement performed on B-mode longitudinal section of the artery.	Same	longitudinal and cross sectional	longitudinal and cross sectional	Identical to predicate	N/A
34	Detection algorithm / other algorithms	Contour tracking algorithm based on edge / border detection operator, in combination with pattern recognition approach	Globally optimal graph search border detection approach [SON98, SON02]	Not Publicly Available	Not Publicly Available	Substantially Equivalent to Predicate	N/A

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35	Identification of cardiac cycle	Yes	Yes	Yes	Yes	Identical to predicate and reference device	N/A
36	Identification of carotid section	Yes	Yes	Yes	Yes	Identical to predicate and reference device	N/A
37	Report Review	Yes	Yes	Yes	Yes	Identical to predicate and reference device	N/A
38	Exam duration time	9 minutes brachial analysis/ 5 minute carotid analysis	Same	same for carotid analysis	same for carotid analysis	Identical to predicate	N/A
39	Target area	Carotid and brachial artery	Same	Carotid	Carotid and other targets such as the heart.	Identical to predicate	N/A
40	Results of the use of the diagnostic device	Results are related to the measurement of well-known and accepted cardiovascular biomarkers.	Same	Not Publicly Available	Not Publicly Available	Identical to predicate	N/A

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		A clinical evaluation has been conducted to review the safety and effectiveness of the use of these biomarkers for cardiovascular diseases risk stratification. Results can supplement the physician's decision-making process. They should be used in conjunction with knowledge of the patient's history and other clinical findings.					
41	Carotid analyzer – accuracy	Agreement with RF based gold-standard [JUM 2010 BIANCHINI et Al]: Bland&Altman analysis (bias value ± standard deviation): IMT 0.006 ± 0.039mm	Signed error mean IMT -0.007 ± 0.07 mm Signed error max IMT -0.07± 0.09 mm	Not Publicly Available	Not Publicly Available	Modified	Differences are not expected to have impact on safety or efficacy.

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		Diameter 0.060 ± 0.110mm Distension 0.016 ± 0.039mm	D and Stiffness accuracy and precision not found				
42	Carotid analyzer – precision	1) Intra-observer intra-session variability: 7%±6% for IMT, 2%±1% for diastolic diameter, 11%±7% for distension, 11%±7% for cross sectional compliance coefficient and 13%±8% for cross sectional distensibility coefficient. 2) Inter-observer intra-session variability: 8%±8% for IMT, 3%±2% for diastolic diameter, 11%±10% for distension, 12%±11% for cross sectional compliance	Intra-subject reproducibility for the mean carotid IMT had a coefficient of variation of 3% with a mean absolute difference of 0.02 mm (SD 0.01). [PAT10]	Not Publicly Available	Not Publicly Available	Modified	Carotid Studio precision expressed as coefficient of variation is 2% for the diameter, 11% for the diameter variation during the cardiac cycle, 6% for IMT for intra-observer intra-session measurements and 3% for the diameter, 12% for the diameter variation during the cardiac cycle, 6% for IMT for intra-observer inter-session measurements. As regards plaque geometric and statistics data the precision of the results expressed as coefficient of variation resulted lower than 10% for each

Item No.	Device Characteristic.	Proposed Device Cardiovascular Suite	Primary Predicate Device Vascular Tools 5	Reference Device: M'Ath Std.	Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH	Comparison Analysis: *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.
		coefficient and 13%±12% for cross sectional distensibility coefficient. 3) intra-observer inter-session variability: 6%±6% for IMT, 3%±2% for diastolic diameter, 12%±10% for distension, 16%±11% for cross sectional compliance coefficient and 17%±12% for cross sectional distensibility coefficient. Data from a single center study Plaque also NB for compliance and distensibility rep also depends on pressure estimation					measurement obtained on a single image by the same operator.

Item No.	**Device Characteristic.**	**Proposed Device Cardiovascular Suite**	**Primary Predicate Device Vascular Tools 5**	**Reference Device: M'Ath Std.**	**Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	**Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.**
43	FMD analyzer - accuracy	Accuracy evaluated on synthetic image sequences: error in assessing % diameter variation equal to 0.013%.	Comparison with a non-automated method (Prosound System, Jet Propulsion Laboratory, USA). Brachial ultrasound tapes from 12 patients undergoing endothelial function assessment The correlation between the two approaches was excellent for both the measurement of absolute diameters (r=0.995, P<0.001) and percentage diameter changes	Not Publicly Available	Not Publicly Available	Modified	Accuracy evaluated on synthetic image sequences: error in assessing % diameter variation equal to 0.013%.Please note as mentioned above that: The results obtained using the two systems have been evaluated in a comparison study [Faita et Al] performed on 60 participants, which showed an excellent level of agreement in vessel edge location and subsequent diameter evaluation . Therefore differences do not change safety or efficacy profile doe to this low rate of difference.

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			(r=0.973, P<0.001). The Brachial Analyzer demonstrated no bias compared with the other method [MAN02]				
44	FMD analyzer - precision	Precision was assessed in terms of reproducibility. Intra-observer intra-session variability: 9.9±8.4% Intra-observer inter-session variability: 12.9±11.6% Data from a multicenter study [REF].	In the above mentioned experimentation Brachial Analyzer demonstrated excellent precision (0.07 mm and 1.62 percentage diameter change). [MAN02]	Not Publicly Available	Not Publicly Available	Modified	FMD-Studio precision, expressed as coefficient of variation, is 10% for intra-observer intra-session measurements and 13% for intra-observer inter-session measurements of FMD%.
45	IEC 62366	Standard Applied to Product	Same	Not Publicly Available	Not Publicly Available	Identical to Predicate	N/A

Item No.	**Device Characteristic.**	**Proposed Device Cardiovascular Suite**	**Primary Predicate Device Vascular Tools 5**	**Reference Device: M'Ath Std.**	**Reference Device: K090461, the IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D CARDIAC PERFORMANCE ANALYSIS 1.0 by TOMTEC IMAGING SYSTEMS, GMBH**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*	**Rationale as to why Modification or Difference from Predicate to Subject Device Does Not Impact Safety and Effectiveness.**
46	IEC 62304	Standard Applied to Product	Same	Not Publicly Available	Not Publicly Available	Identical to Predicate	N/A

The modifications between the Cardiovascular Suite 4.2.1 and the Vascular Tools 5 predicate are examined in detail above. Quipu SRL determined that each difference between the devices resulted in no impact to the performance, safety, or efficacy of Cardiovascular Suite 4.2.1 when compared to Vascular Tools 5.

5.7 Sterilization and Shelf Life

The Cardiovascular Suite 4.2.1 is a software only and therefore, does not require sterilization and has no patient contacting surface. Therefore no Sterilization or Shelf life testing was conducted.

5.8 Biocompatibility

The Cardiovascular Suite 4.2.1 is a software only and therefore, does not include any patient contacting materials. Therefore no biocompatibility testing was conducted.

5.9 Product Performance Testing - Software

Performance Software tests of Cardiovascular Suite 4.2.1 have been performed. The passing results from the performance bench testing demonstrate that Cardiovascular Suite 4.2.1 has met the functional requirements and is substantially equivalent to the predicate device.

5.10 Application of Standards

The following standards are applicable to the Cardiovascular Suite 4.2.1.

Table 5: Applied Standards

Original Order	Standards Applied No.	Standards Title	Equivalent ISO / IEC Version
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes	ISO 13485:2016
2	EN ISO 14971:2012	Application of risk management to medical devices	ISO 14971:2007
3	EN 1041:2008 + AMD1:2013	Information supplied by the manufacturer of medical devices	N/A
4	EN 62304:2006 + AMD1:2015	Medical device software - Software life cycle processes	IEC 62304:2006 + AMD1:2015
5	EN 62366:2008	Medical devices - Application of usability engineering to medical devices	IEC 62366:2007

Original Order	Standards Applied No.	Standards Title	Equivalent ISO / IEC Version
6	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1:2016

5.11 Validation Testing of Measurements for the Cardiovascular Suite 4.2.1

Validation testing of the measurements available in the Cardiovascular Suite 4.2.1 were performed and are summarized here.

Precision of the FMD Studio module

The precision of the FMD Studio module was assessed in terms of repeatability of the measurement and tested in seven Italian centers, recruiting 135 healthy volunteers aged between 20 and 60. On each subject two different types of repeatability tests were performed:

i) intra-observer intra-session: in this case the same operator has analyzed the same subject twice within the same session, with a time interval of one hour;

ii) intra-observer inter-session: in this case the operator has analyzed the same subject twice within two different sessions, with a time interval of three days.

Precision of the Carotid Studio module

For the Carotid Studio module, sequences of the right/left common carotid artery of 10 healthy volunteers were analyzed during two separate sessions after 7 days. In the first session two Clinical Operators (Opr 1 and Opr 2) measured each vessel three times each. During the second session, only Opr 1 repeated the analysis. On each sequence of images, the following elements were calculated automatically through the Carotid Studio: Intima-media thickness (IMT), diastolic diameter (Dd), distension (ΔD), cross-sectional compliance (CC) coefficient and cross-sectional distensibility coefficient (DC).

Compatible ultrasound devices.

A further test was carried out to verify that the claimed accuracy of the CardioVascular Suite (CVS) software is maintained with claimed compatible ultrasound devices.

Scans of both the Carotid artery and the Brachial artery in longitudinal section were used for the test. Both online and offline analysis setup were tested. For the online setup, the ultrasound images were acquired by the CVS software using

the Epiphan AV.io HD frame grabber. For the offline setup, images were exported as multimedia file from the ultrasound device and imported in the CVS software by using an external USB flash memory.

Site of scan	US modality	# of images (online / offline)
Carotid artery	B-mode	120 (60/60)
Brachial artery	Dual (B-mode + PWD)	120 (60/60)

The accuracy of the following measurement of the CVS software was evaluated:

- Diameter (D)
- Intima Media Thickness (IMT)
- Time Average of the Doppler Flow Velocity (TADFV)

The accuracy of the Shear Rate (SR) was estimated as the root mean square of the errors of the TADFV and the D measurements.

The measurements were carried out by our software and compared with gold-standard measurements manually obtained by an expert.

The analysis of accuracy was carried out on the full set of images. The agreement between the CVS software and the Gold Standard was tested by the analysis of the Coefficient of Variation (ratio of the standard deviation to the mean of the measurements). In addition, each sub-set of images coming from each of the 15 devices was singularly analyzed in order to better identify specific issues that might be related to the single ultrasound device.

Intra-session variability between measurements of the Time Average of the Doppler Flow Velocity was also evaluated.

RESULTS

FMD-Studio precision, expressed as coefficient of variation, is 10% for intra-observer intra-session measurements and 13% for intra-observer inter-session measurements of FMD%. For the Shear Rate measurement, the estimated precision is 2,3%.

Carotid Studio precision expressed as coefficient of variation is 2% for the diameter, 11% for the diameter variation during the cardiac cycle, 6% for IMT for intra-observer intra-session measurements and 3% for the diameter, 12% for the diameter variation during the cardiac cycle, 6% for IMT for intra-observer inter-session measurements. As regards geometric and statistics data the precision of the results expressed as coefficient of variation resulted lower than 10% for each measurement obtained on a single image by the same operator.

These results are maintained for each compatible ultrasound device.

5.12 Conclusion

The subject device Cardiovascular Suite 4.2.1 is substantially equivalent to the predicate device. Cardiovascular Suite 4.2.1 shares a substantially equivalent design, indications for use and technology (i.e. features, materials, and principles of operation) with the predicate device and no new elements pertaining to change in safety or effectiveness have been identified.