



March 31, 2025

TribusMed Beheer BV
Johan Vogelaar
COO
Oude Vest 9
Breda, 4811HR
Netherlands

Re: K242166
Trade/Device Name: TribusConnect
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: July 24, 2024
Received: February 24, 2025

Dear Johan Vogelaar:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb" is positioned over a light blue, semi-transparent logo of the letters "FDA".

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K242166

Device Name

TribusConnect

Indications for Use (Describe)

TribusConnect is a medical image management and processing device which facilitates remote viewing on different locations of CT images stored in DICOM format, allowing healthcare professionals to access, review, manipulate, measure and visualize simulated patient data from different sources.

TribusConnect is suitable for, but not limited to, pre-procedural planning of cardiac interventions and post procedural analysis of cardiac interventions.

To facilitate the above, TribusConnect uses CT DICOM data to output volume renderings, ML-based heart segmentation, a simulated fluoroscopy view, endo views, MIP and MPR views.

Measurements can only be performed on MPR views.

TribusConnect is not intended for diagnostic use on mobile displays.

TribusConnect is not intended to serve as the primary archive for medical imaging data.

TribusConnect is an adjunct tool and is not intended to replace a physician's own review on the images.

The intended patient population is comprised of adult patients (22 years of age and older)

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TribusConnect 510(k) Summary (K242166)

The following 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act 1990 and 21 CFR 807.92.

Date: March 30, 2025

Contact details

Applicant Name: TribusMed Beheer BV

Applicant Address: Oude Vest 9 Breda 4811HR Netherlands

Applicant Contact Telephone: +31 6 36192511

Applicant Contact: Johan Vogelaar

Applicant Contact Email: johan.vogelaar@tribusmed.com

Device

Device Trade Name: TribusConnect

Classification Name: Medical image management and processing system

Common Name: Automated Radiological Image Processing Software

Regulation Number: 21 CFR 892.2050

Product Code(s): QIH, LLZ

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141061	RemotEye Viewer	LLZ
K222593	TruPlan Computed Tomography (CT) Imaging Software	QIH

Device Description Summary

TribusConnect consists of the following components:

- The **cloud component** performs rendering, provides access to imaging data, ensures secure user authentication, and safeguards data with encryption both in transit and at rest.
- The **web-based viewer application** is accessible through standard web browsers on desktops, tablets, and mobile devices.

The device has only one model.

TribusConnect is a cloud-based software application that facilitates remote viewing on different locations of CT images stored in DICOM format, allowing healthcare professionals to access, review, manipulate, measure and visualize simulated patient data from different sources through a secure internet connection. TribusConnect offers a secure and efficient solution for accessing, reviewing, and visualizing CT images in DICOM format. Measurements can be performed on MPR views. TribusConnect is

provided to its users as a SaaS solution, TribusMed will be in control of installation, configuration, updates etc.

TribusConnect can be used in healthcare facilities, hospitals, and remote locations, including home environments, when accessed by authorized users through a secure internet connection.

CT scans can be uploaded to the server and will be de-identified before the upload. On the server the heart structures will be segmented using a ML based algorithm. Also a ML based semi-automated localization of the Left Atrial Appendage (LAA) will be performed.

All rendering of image data is done on the server the results can be viewed on standard computing devices (e.g., desktop, laptop, tablet, smartphone) with an internet connection.

Images can be rendered as Volume rendering, segmentations, simulated fluoroscopy, endo view, MIP or MPR. The user can interact with the data like zooming, rotating, changing the window. On the MPR views measurements can be performed.

The device's cloud infrastructure and encryption protocols ensure data protection and compliance with security standards.

protection and compliance with security standards. The client operates on standard computing devices (e.g., desktop, laptop, tablet, smartphone) with an internet connection and requires no dedicated energy source as it leverages the user's device power.

TribusConnect is a software application that does not involve physical materials with patient contact and operates through cloud infrastructure and standard web browsers.

TribusConnect is supported in the following configurations:

- PC: Windows with Edge or Chrome
- Mac: MacOS with Safari or Chrome
- iPad: iPadOS with Safari or Chrome
- iPhone: iOS with Safari or Chrome
- Tablet: Android with Chrome
- Smartphone: Android with Chrome

Note: TribusConnect is not intended for diagnostic use on mobile displays.

For interacting with TribusConnect the following internet bandwidth is recommended:

Upload: 5 Mbps

Download: 20 Mbps

The software provides the following Manual Quantitative Imaging Functions. These measurements can be used on the MPR views only. The accuracy of all measurements is within 5% of the true value.

Measurement	Results
Distance measurement	Distance between two points in mm
(Open) spline	Distance over a non-straight trajectory in mm
Closed spline	Area in mm ² , perimeter, area derived diameter, perimeter derived diameter, min diameter and max diameter all in mm
Angle	Angle in degrees
Hounsfield probe (3D Marker)	The HU (Hounsfield unit) of the underlying pixel

Intended Use/Indications for Use

Intended Use

TribusConnect is a cloud-based DICOM viewer designed for medical professionals to securely access, review, manipulate, measure and visualize DICOM images. The software is intended to be used by trained healthcare professionals, including but not limited to radiologists, physicians, nurses, and technicians.

Indications for use

TribusConnect is a medical image management and processing device which facilitates remote viewing on different locations of CT images stored in DICOM format, allowing healthcare professionals to access, review, manipulate, measure and visualize simulated patient data from different sources.

TribusConnect is suitable for, but not limited to, pre-procedural planning of cardiac interventions and post procedural analysis of cardiac interventions.

To facilitate the above, TribusConnect uses CT DICOM data to output volume renderings, ML-based heart segmentation, a simulated fluoroscopy view, endo views, MIP and MPR views.

Measurements can only be performed on MPR views.

TribusConnect is not intended for diagnostic use on mobile displays.

TribusConnect is not intended to serve as the primary archive for medical imaging data.

TribusConnect is an adjunct tool and is not intended to replace a physician's own review on the images.

The intended patient population is comprised of adult patients (22 years of age and older)

Comparison with predicate devices:

The detailed analysis of the subject device and the primary and secondary predicate devices (shown in the Device comparison table) demonstrates that the subject device is substantially equivalent in indications for use / intended use, technological characteristics, functionality, and operating principles with the primary predicate (K141061) and with the secondary predicate (K222593). Of the three characteristics (technical, biological, and clinical) required for the demonstration of equivalence, biological characteristics are not applicable since the subject device and both predicate devices are software as a medical device application with no tangible component interfacing with the body.

Device comparison table

	TribusConnect (Subject device)	RemotEye Viewer (Primary Predicate)	TruPlan (Secondary Predicate)
Device name	TribusConnect	RemotEye Viewer	TruPlan Computed Tomography (CT) Imaging Software
Device manufacturer	TribusMed BV	NeoLogica s.r.l.	Circle Cardiovascular Imaging Inc.
510(k) number	K242166	K141061	K222593
Regulation name	Medical image management and processing system	Picture archiving and communications system	Medical image management and processing system
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product code	QIH	LLZ	QIH, LLZ
Regulatory Class	II	II	II

	TribusConnect (Subject device)	RemotEye Viewer (Primary Predicate)	TruPlan (Secondary Predicate)
Intended use	TribusConnect is a cloud-based DICOM viewer designed for medical professionals to securely access, review, manipulate, measure and visualize DICOM images. The software is intended to be used by trained healthcare professionals, including but not limited to radiologists, physicians, nurses, and technicians.	The RemotEye Viewer software product is intended to be used as a functional, web based medical image viewer to download, review, interpret, manipulate, visualize and print medical multi-modality image data in DICOM format also stored in remote locations with respect to the viewing site. When interpreted by a trained physician, the medical images displayed by RemotEye Viewer can be used as an element for diagnosis. Typical users of RemotEye Viewer are trained professionals, including but not limited to radiologists, physicians, nurses and technicians.	TruPlan enables visualization and measurement of structures of the heart and vessels for: <ul style="list-style-type: none"> - Pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure - Post-procedural evaluation for the LAAC procedure

	TribusConnect (Subject device)	RemotEye Viewer (Primary Predicate)	TruPlan (Secondary Predicate)
Indications for use	<p>TribusConnect is a medical image management and processing device which facilitates remote viewing on different locations of CT images stored in DICOM format, allowing healthcare professionals to access, review, manipulate, measure and visualize simulated patient data from different sources. TribusConnect is suitable for, but not limited to, pre-procedural planning of cardiac interventions and post procedural analysis of cardiac interventions.</p> <p>To facilitate the above, TribusConnect uses CT DICOM data to output volume renderings, ML-based heart segmentation, a simulated fluoroscopy view, endo views, MIP and MPR views. Measurements can only be performed on MPR views.</p> <p>TribusConnect is not intended for diagnostic use on mobile displays. TribusConnect is not intended to serve as the</p>	<p>The RemotEye Viewer software product is intended to be used as a functional, web based medical image viewer to download, review, interpret, manipulate, visualize and print medical multi-modality image data in DICOM format also stored in remote locations with respect to the viewing site. When interpreted by a trained physician, the medical images displayed by RemotEye Viewer can be used as an element for diagnosis. Typical users of RemotEye Viewer are trained professionals, including but not limited to radiologists, physicians, nurses and technicians.</p>	<p>TruPlan enables visualization and measurement of structures of the heart and vessels for:</p> <ul style="list-style-type: none"> - Pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure - Post-procedural evaluation for the LAAC procedure

	TribusConnect (Subject device)	RemotEye Viewer (Primary Predicate)	TruPlan (Secondary Predicate)
	<p>primary archive for medical imaging data. TribusConnect is an adjunct tool and is not intended to replace a physician’s own review on the images.</p> <p>The intended patient population is comprised of adult patients (22 years of age and older)</p>		
Patient population	The intended patient population is comprised of adult patients (22 years of age and older)	<p>No limitations in 510(k) or IFU</p> <p><i>Similar, The fact that a portion of the population is not within the scope of TribusConnect does not introduce new risks.</i></p>	<p>TruPlan’s intended patient population is comprised of adult patients.</p> <p><i>Same</i></p>
Input data	CT (In DICOM format)	<p>Multi modality DICOM compliant (Including CT)</p> <p><i>Similar, more supported modalities</i></p>	<p>CT (In DICOM format)</p> <p><i>Same</i></p>

	TribusConnect (Subject device)	RemotEye Viewer (Primary Predicate)	TruPlan (Secondary Predicate)
Patient study management	<ul style="list-style-type: none"> • Study/series previewing • Exporting • Deleting • Anonymizing • Search 	<ul style="list-style-type: none"> • Study/series previewing • Exporting • Deleting • Anonymizing • Search <p><i>Same</i></p>	<ul style="list-style-type: none"> • Study/series previewing • Exporting • Deleting • Anonymizing • Search <p><i>Same</i></p>
Measurement functionality	<ul style="list-style-type: none"> • Distance (length, diameter, perimeter) • Area • Angle • Signal intensity 	<p>Advanced distance, area, angle and density measurement tools (including SUV for PET images), plus several graphical annotation tools.</p> <p>Measurement of CTR (Cardio-Thoracic Ratio) also supported.</p> <p><i>Same</i></p>	<ul style="list-style-type: none"> • Distance (length, diameter, perimeter) • Area • Angle • Signal intensity • Coordinates <p><i>Same</i></p>
Visualization/rendering	<ul style="list-style-type: none"> • 2D • 3D • 4D • MPR • Annotations • Segmented 3D volume 	<ul style="list-style-type: none"> • 2D • 3D • MPR / MIP / MinIP /AvgIP • Annotations <p><i>Similar. No information could be found whether 4D is supported, since 4D as implemented in TribusConnect and TruPlan is a sequence of 3D images played in a movie, this will not introduce a new risk</i></p>	<ul style="list-style-type: none"> • 2D • 3D • 4D • MPR • MIP • Annotations • Segmented 3D volume <p><i>Same</i></p>
Segmentations	ML based segmentation of all heart chambers, aorta, pulmonary trunk and vena cava	No segmentation	ML based segmentation left atrium, left ventricle, left atrial appendage and the aorta. (Left

	TribusConnect (Subject device)	RemotEye Viewer (Primary Predicate)	TruPlan (Secondary Predicate)
			heart) Manual sculpting <i>Similar, The same underlying technique is used the algorithm in TribusConnect is trained to identify more structures, this does not introduce new risks. Absence of the sculpting feature does not introduce new risks.</i>
Left atrial appendage localization	Semi-Automated Localization of LAA appendage	No such functionality	Localization of LAA appendage <i>Similar, since TribusConnect does not automatically suggest measurements like TruPlan, no new risks are introduced.</i>
Session saving	Analysis is stored in a "Saved session"	DICOM presentation states and Key note images <i>Similar, the saved sessions in TribusConnect also contain information about the orientation of the MPR planes and volumes, this does not introduce new risks</i>	Analysis is saved in a saved session. Same
Collaboration	Shared sessions	Cloud-based peer-to-peer image sharing functionalities.	Sessions are saved on a central location and available for other users.

	TribusConnect (Subject device)	RemotEye Viewer (Primary Predicate)	TruPlan (Secondary Predicate)
		<i>Same</i>	<i>Similar, work can be shared via a saved session, but no “live” image sharing, this does not introduce new risks</i>
Upload of data	File system based upload of DICOM files.	DICOM protocol and import from disk <i>Same</i>	Supports DICOM connectivity and file-system based upload of image data. <i>Same</i>
Storage of data	Cloud	Cloud <i>Same</i>	Laptop, on-premise server <i>Similar, an on-premise server is not necessarily accessible via the internet, the risks introduced by the cloud component are handled in the cyber security risk assessment and deemed acceptable</i>
Technical environment	Cloud based zero footprint viewer, users can access the viewer through a standard web browser on their desktops, laptops, or mobile devices.	RemotEye Viewer is compatible with Windows, Mac OS X and Linux clients. <i>Similar, TribusConnect is supported on more devices, the possible risks introduced by this are evaluated as part of the risk management activities and deemed acceptable</i>	Windows/Apple based desktop/laptop application. <i>Similar, TribusConnect is supported on more devices and cloud based, the possible risks introduced by this are evaluated as part of the risk management activities and deemed acceptable</i>

Predicate device discussion

Indications for Use Comparison

TribusConnect and the primary predicate device, RemotEye Viewer (K141061), share the same indications for use, both facilitating web-based image viewing. While TribusConnect supports fewer imaging modalities and has a more limited intended patient population, performance testing confirmed that these differences do not compromise safety or effectiveness. Validation studies demonstrated equivalent diagnostic image quality, usability, and accuracy in supported modalities, ensuring consistent clinical performance. Therefore, these differences do not introduce new risks.

The secondary predicate device, TruPlan (K222593), is specifically intended for LAAC procedures. TribusConnect supports a broader range of cardiac interventions using similar imaging and measurement techniques, with a consistent patient population. Validation of the algorithm confirmed equivalent performance, and no new risks were identified. Therefore, the intended use of TribusConnect is very similar to that of TruPlan, and these differences do not introduce new risks.

Technological Comparison

Visualization Techniques and Measurements:

Both TribusConnect and RemotEye Viewer offer the same range of visualization techniques and measurements. This suggests parity in their basic functionalities for viewing medical imaging data.

Web-based Platforms:

Both TribusConnect and RemotEye Viewer are web-based viewers, meaning they can be accessed remotely via browsers.

Modalities Supported:

TribusConnect supports only CT scans, while RemotEye Viewer supports multiple modalities. This provides more flexibility with RemotEye Viewer but does not introduce new risks according to verification and validation tests.

Heart Segmentation:

TruPlan uses machine learning to segment four heart structures, while TribusConnect uses ml to identify seven. Despite the difference in the number of structures identified, validation shows that TribusConnect does not introduce any new safety or performance issues.

LAA Localization Tool:

The LAA localization method in TruPlan is designed for initiating a landingzone measurement. In TribusConnect, the method is used as a navigation tool only. This distinction does not introduce new risks, reinforcing the system's safety.

Overall Evaluation of the technological comparison :

Both systems maintain similar levels of safety and performance. TribusConnect does not introduce new technological characteristics, staying within previously validated boundaries. Its additional functionalities, like supporting more heart structures does not introduce new risks. Therefore, TribusConnect offers comparable performance and safety without new technological changes.

Regulatory History

Currently, no warning letters, product recalls, or reports in the MAUDE database have been identified for either RemotEye Viewer or TruPlan.

Conclusion of the Predicate device discussion

Based on the substantial similarities in intended use, technical characteristics, and the use of equivalent segmentation techniques, along with the absence of regulatory concerns for the predicate devices, TribusConnect is deemed substantially equivalent. It is concluded that TribusConnect does not introduce any new issues and is as safe and effective as the predicate devices, RemotEye Viewer and TruPlan.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Performance testing was conducted to verify compliance with specified design requirements in accordance with IEC 62304:2015, ISO 14971:2019, and NEMA 3.1-3.20 (2016) DICOM standard.

Software Verification:

A test plan was created and executed to ensure that all requirements were implemented according to specifications, and all test cases passed successfully. Manual measurements were thoroughly validated using phantom studies, demonstrating that all performance criteria were met, with measurement results falling within 5% of the true value.

Verification testing was conducted to confirm the device's specifications and performance in accordance with the FDA guidance documents:

- Content of Premarket Submissions for Device Software Functions
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions

Cybersecurity Testing:

A penetration test was conducted by an external company, and the cybersecurity assessment was successfully completed, validating the system's security measures and resilience. No issues classified as medium or higher were identified.

Cybersecurity testing was performed in accordance with the FDA guidance document:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Validation of the machine learning based algorithms:

For the validation of the algorithms, 100 CTA volumes were collected from 14 sites across the United States. No specific patient selection criteria were applied, and the volumes from each site generally consisted of consecutive cases. The data, retrospectively gathered, was anonymized before being shared with TribusMed.

The sites providing data for the training dataset are different from the validation dataset, that is, no sites used for training are used for validation. Each dataset is acquired from a unique patient.

Details dataset used

- Patients - 100
- Male - 59
- Female - 40
- Unknown - 1
- Age (y) - 76 (52 - 91)
- Slice thickness (mm) - 0.63 (0.50 - 2.50)
- Slice count - 303 (106 - 868)
- In-plane resolution (mm) - 0.49 (0.30 - 0.87)
- Field Of View (mm) - 160 (103 - 347)
- Tube potential (kVp) - 120 (70 - 135)
- X-ray tube current (mA) - 571 (101 - 2442)
- LAA morphology
 - Chicken Wing - 42
 - Cactus - 42
 - Windsock - 14
- LAA Thrombus / Bad Filling - 18
- Manufacturers:
 - Toshiba /Canon - 12
 - Philips - 6
 - Siemens - 42
 - GE - 38

Validation of Heart segmentation

Acceptance criteria **Heart segmentation**:

- In at least 80% of cases bone removal should be performed correctly
- In at least 80% of cases each segmented structure should be clearly visible
- In at least 80% of cases the rendered view of the heart should be clinically usable

Validation of Heart segmentation is performed by 2 US board certified radiologists who qualitatively evaluated the performance.

Validation results Heart segmentation:

- 100% of cases bone removal correct
- 99% of cases each segmented structure is clearly visible
- 100% of cases the rendered view of the heart is clinically usable

Due to this low failure rate, a subgroup analysis would not provide meaningful insight

Validation of LAA Localization

Acceptance criteria **LAA Localization**:

- LAA localized within 10mm of the landing zone contour center as computed by the predicate device, in 95% of all cases, with a confidence of 95% and a statistical power of 80%

Validation of the LAA localization feature is performed by comparing the results with the predicate device TruPlan(K222593)

Acceptance criteria LAA Localization:

- 97% of the cases are within 10mm of the landing zone contour center as computed by the predicate device

Validation results of the LAA localization feature:

Average distance was 4.40 mm, and its standard deviation was 2.74 mm. 95 out of 98 cases (97%) had a distance < 10 mm while the maximum distance was 12.2 mm.

Based on subgroup analysis it is concluded that the method can be deemed generalizable, reliable, and suitable for use across all tested condition

As stated above, the heart segmentation and LAA localization features have been validated on scans with the following characteristics:

Scanner manufacturers: Toshiba/Cannon, Philips, Siemens, GE

Slice thickness (mm): 0,50-2,50

Slice count :106-868

In-plane resolution (mm): 0,30-0,87

Field Of View (mm): 103-347

Tube potential (kVp): 70-135

X-ray tube current (mA): 101-2442

For a safe and effective outcome of the Heart Segmentation and LAA localization, the parameters of the scan used should fall within the specified ranges or match the provided list, as detailed in the table above.

Clinical testing:

As stated above the validation of the ML algorithms is performed retrospectively on clinical scans. The segmentations have been validated by physicians.

Further no clinical studies were necessary to support substantial equivalence.

Conclusion:

The information submitted in this premarket notification, including performance testing and predicate device comparisons, demonstrates that TribusConnect is at least as safe and effective, and performs at least as well as the legally marketed predicate devices K222593 and K141061.