



April 4, 2025

QFR Solutions bv
% Bob Goedhart
Head of QARA
Schuttersveld 9
LEIDEN, ZH 2316XG
NETHERLANDS

Re: K243769
Trade/Device Name: QFR (3.0)
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: QHA, LLZ
Dated: December 6, 2024
Received: March 5, 2025

Dear Bob Goedhart:

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,



Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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)

K243769

Device Name

QFR (3.0)

Indications for Use (Describe)

QFR is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease.

When the quantified results provided by QFR are used in a clinical setting on X-ray images of an individual patient. The results are only intended for use by the responsible clinicians.

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

Summary in accordance with the requirements of 21 CFR Part 807.92(a).

Submitter

Manufacturer : QFR Solutions bv
Address : Schuttersveld 9, 2316 XG Leiden, The Netherlands
Contact Person : B. Goedhart, Head of QARA
Date Prepared : April 4, 2025
Email : bgoedhart@qfrsolutionsglobal.com
Telephone : +31 71 522 3244
Fax : +31 71 521 5617

Device

Device Name : QFR (3.0)
Common Name : QFR (3.0)
Classification Name : Angiographic X-ray system
Regulatory Class : II
Regulation : 21 CFR 892.1600
Classification Product Code : QHA
Subsequent Product Code : LLZ

Predicate Device

Predicate Device : QANGIO XA 3D (K182611)

This predicate device has not been subject to a design-related recall.

Device Description

QFR is delivered as a standalone software package which is installed and running on a server system in the server room of the cathlab or the hospital. The server offers all functionalities that are required to work with the quantitative measurement in X-ray Angiographic (XA) patient studies supported by the QFR device.

QFR will be used by interventional cardiologists and researchers to obtain quantifications of lesions in coronary vessels. QFR has been developed as a web-based

application to run in a web browser in the control room of the cathlab or in a hospital image review room. The import of images and the export of analysis results are via PACS.

The QFR device calculates the QFR value based on an anatomical model which is the result of a 3D reconstruction using the 2D contours obtained from two angiographic projections with angles $\geq 25^\circ$ apart. These projections are acquired through monoplane or biplane XA systems. The algorithm involves three key steps: (1) Vessel Selection, (2) Contours Detection, and (3) QFR Analysis:

1. Vessel Selection: Angiograms are pre-classified by a deep learning model, identifying main epicardial vessels such as RCA, LAD, and LCx. The user then chooses the segment for analysis, and the software automatically selects end-diastolic image frames. The end-diastolic frame is determined as the angiogram frame with the vessel lumen adequately filled with contrast in both image sequences. This selection is either based on the patient's electrocardiogram when available or performed by the software using a deep learning model. It is essential for the user to verify this selection before proceeding with the analysis. The chosen end-diastolic frame serves as the projection view for the subsequent 3D reconstruction of the vessel.

2. Contours Detection. First, the system runs another deep learning model for coronary vessel segmentation as input to identify anatomical corresponding points on both projections for automatic correction of the system distortions introduced by the isocenter offset and the respiration-induced heart motion. Second, begins the automatic detection of start and end positions of the vessel segment to be reconstructed on the projection views, and extract its contours and centerline. Third, the position of the start and end point must be confirmed by the user.

3. QFR Analysis: The QFR value is computed from the arterial and reference diameter function calculated from the 3D reconstruction based on the contours detected on the cross-sections of the vessel segment, and the patient-specific volumetric flow rate calculated from the automated TIMI frame count. The reference diameter and bifurcations are used to determine the flow distribution at coronary bifurcations and calculate the reference diameter function. The reconstructed 3D model is used to calculate the QFR value.

A report is generated by QFR that shows patient information, image acquisition information (both obtained from the DICOM input), analysis results (vessel sizing and QFR value) and snapshot images showing the vessel boundaries.

Intended Use

QFR is software intended to be used for performing calculations in X-ray angiographic images of the coronary arteries. QFR enables interventional cardiologists and researchers to obtain quantifications of one or more lesions in the analyzed coronary vessel segment. In particular, QFR provides:

- Quantitative results of coronary vessel segments based on a 3D reconstructed model;
- Dimensions of the cardiovascular vessels and lesions;
- Quantification of the pressure drop in coronary vessels.

Indications for Use

QFR is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease.

When the quantified results provided by QFR are used in a clinical setting on X-ray images of an individual patient, the results are only intended for use by the responsible clinicians.

Comparison of Technological Characteristics with the Predicate Device

Substantial Equivalence Information

The predicate device is QANGIO XA 3D (K182611).

Intended Use and Indications for Use of the QFR device are identical to those of the predicate device.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE	SUBJECT DEVICE: QFR (K243769)	PREDICATE DEVICE: QANGIO XA 3D (K182611)
Regulation	892.1600 – Angiographic X-ray System	892.1600 – Angiographic X-ray System
Product Code	QHA (Class 2) – X-ray Angiographic Imaging Based Coronary Vascular Simulation Software	QHA (Class 2) – X-ray Angiographic Imaging Based Coronary Vascular Simulation Software
Associated Product Code	LLZ	LLZ
Image modality	XA	XA
Input format	DICOM	DICOM
Patient study browser (used to select the patient study of interest)	Yes	Yes
Import study from PACS	Yes	Yes
Automated series loading	Yes	Yes
Interactive image handling (incl. windowing, zooming, panning, filtering, window-level)	Yes	Yes

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE	SUBJECT DEVICE: QFR (K243769)	PREDICATE DEVICE: QANGIO XA 3D (K182611)
Cine loop review with controls for speed, and frame-by-frame review.	Yes	Yes
ECG display (used for ECG signal display in synchrony with the review of the XA images)	Yes	Yes
ISO center calibration (provided by the manufacturer of the X-ray acquisition equipment)	Yes	Yes
Possibility to edit or delete an existing analysis	Yes	Yes
Multiple analyses possible on a single image	Yes	Yes
Report facility	Yes	Yes
Export results to PACS	Yes	Yes
Audit Trail	Yes	Yes
Guided workflow supporting step-by-step analysis	Yes	Yes
Selection of the angiographic series to be used in the analysis	Selection is now supported by an AI/ML model and manual correction	Only supported manual selection
Selection of the determination of the start and end points of the vessel to be analyzed	Selection is now supported by an AI/ML model and manual correction	Only supported manual selection

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE	SUBJECT DEVICE: QFR (K243769)	PREDICATE DEVICE: QANGIO XA 3D (K182611)
Determination of the ED frame within the series to be used	Selection is now supported by a combination of an AI/ML model and an analytical algorithm using the ECG data and manual correction	Only supported manual selection
Determination of start and end frame for flow velocity calculation	Automatic determination of the start and end frame is now supported by an analytical algorithm based on traditional image processing techniques or manual indication	Only supported manual indication of the start and end frame

Performance Data

QFR algorithm improvements

Performance evaluation of vessel classification: Since this functionality aims at supporting the user and not to completely automate the functionality, an acceptance criterion of 80% for correct vessel classification was defined. For the vessel classification the following performance measures were obtained: 96% of the patient studies showing the RCA were selected correctly, 88% of the patient studies showing the LAD were selected correctly and 78% of the patient studies showing the LCX were selected correctly. On average the 80% acceptance criterion was satisfied.

Performance evaluation of start and end point detection: Since this functionality aims at supporting the user and not to completely automate the functionality, an acceptance criterion of 80% for correct start and end point detection was defined, where only 10% is allowed to be completely wrong. The performance of the AI/ML model using the image data performed 77% correct result, 11% showed a small deviation (needed no correction), 8% showed a wrong result (needed correction) and 4% gave no result in a representative dataset. In conclusion, 88% satisfies the 80% criterion and 8% satisfies the 10% criterion.

Performance evaluation: The same acceptance criteria were used for both the analytical algorithm as well as the trained AI/ML model: Since this functionality aims at

supporting the user and not to completely automate the functionality, an acceptance criterion of 80% for correct detection of the ED was defined. The performance of the analytical algorithm using the ECG data performed 83% on a representative dataset. The performance of the AI/ML model using the image data performed 81% on a representative dataset.

Performance evaluation of the new flow velocity calculation: Since this functionality is directly related to the QFR outcome, an acceptance criterion was defined based on the QFR results. A validation process established acceptance criteria that were significantly stricter for the resulting QFR measurement than the reproducibility of FFR measurements. This ensured that, the automatic flow calculation, was not outperformed by manual indication.

For all of these algorithmic improvements the user is able to review and correct the results before the QFR value is calculated.

Conclusions

The QFR device has the same intended use and indications for use as the predicate device QANGIO XA 3D.

The QFR device complies with international process standards (ISO 13485, ISO 14971, IEC 62304, IEC 62366 and ISO 15223).

Testing and validation have produced results consistent with design input requirements. The non-clinical performance data demonstrates that the QFR device performs as intended in the specified use conditions and thereby performs comparable to its predicate device QANGIO XA 3D.

Based on the clinical performance data as documented above, the QFR device was found to perform as intended in the specified use conditions and thereby performs comparable to its predicate device QANGIO XA 3D.

During the development, potential hazards were controlled by a risk management plan, including risk analysis, risk mitigation, verification and evaluation. Results have been summarized in the risk management report and cybersecurity assessment report.

QFR Solutions bv concludes that QFR is a safe and effective medical device and performs comparable to its predicate device QANGIO XA 3D.