August 29, 2025

Nurea
Maxime Cornuau
Quality Assurance and Regulatory Affairs Manager
213 cours Victor Hugo
Bègles, 33130
France

Re: K243859
Trade/Device Name: PRAEVAorta®2
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 30, 2025
Received: July 30, 2025

Dear Maxime Cornuau:

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,

for

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software 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

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)*
K243859

Device Name
PRAEVAorta®2

Indications for Use *(Describe)*
PRAEVAorta®2 is a software intended to be run on its own or as part of another medical device to automatically calculate maximum diameters of anatomical zones from a DICOM CT image containing blood vessels.
PRAEVAorta®2 is designed to measure the maximal transverse diameter of vessels and determine the maximal general diameter using a non-adaptative machine learning algorithm.
Intended users of the software are aimed to the clinical specialists, physicians or other licensed practitioners in healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services. Any results obtained from the software by an intended user other than a physician must be validated by the physician responsible of the patient.
The system is suitable for adults. Its results are not intended to be used on a standalone basis for clinical decision making or otherwise preclude clinical assessment of any disease.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5

510(k) SUMMARY

1. ADMINISTRATIVE INFORMATION

Submitter Name	Nurea
Adress	213 Cours Victor Hugo 33130 Bègles, FRANCE
Phone Number	+33 7 49 24 63 67
Fax number	NA
Company Representative	Maxime CORNUAU
Additional Company Representatives	NA
Email	contact@nurea-soft.com
Date Summary Prepared	August 06, 2025

2. SUBJECT DEVICE INFORMATION

Trade Name	PRAEVAorta®2
Subject Device K Number	K243859
Common Name	Automated radiological image processing software
Product Code	QIH
Regulation Number	21CFR 892.2050
Regulatory Class	Class II
Review Panel	Radiology

3. PREDICATE DEVICE INFORMATION

Predicate Device Name	CT Cardiomegaly
Predicate Device K Number	K232613
Common Name	Automated Radiological Image Processing Software
Product Code	QIH
Regulation Number	892.2050
Regulatory Class	Class II
Review Panel	Radiology

4. DEVICE DESCRIPTION

PRAEVAorta®2 is a decision-making support software for diagnosis and follow-up of vascular diseases. It is intended for automatic segmentation and geometric analysis of vessels.

It is a companion software whose purpose is to accompany the doctor in the first assessment of several indicators from CT scan images

The software is able to reconstruct automatically the vascular structures from CT (Computerized Tomography) scans images and automatically segments aneurysms and associated thrombus.

With this reconstruction, the software is able to provide diameters, volumes, and angles. In addition, the software provides diameters, volumes, angles and distances between anatomic points.

This software is cloud based or can be installed on premises. PRAEVAorta®2 is a server software usable through APIs. However, it is hardly recommended to use it via a client software. The client aims to provide a user interface to send images and receive the analysis results. It can either be a web client, a getaway / PACS client, an integrating solution, or a marketplace

5. INDICATIONS FOR USE

PRAEVAorta®2 is a software intended to be run on its own or as part of another medical device to automatically calculate maximum diameters of anatomical zones from a DICOM CT image containing blood vessels.

PRAEVAorta®2 is designed to measure the maximal transverse diameter of vessels and determine the maximal general diameter using a non-adaptative machine learning algorithm.

Intended users of the software are aimed to the clinical specialists, physicians or other licensed practitioners in healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services. Any results obtained from the software by an intended user other than a physician must be validated by the physician responsible of the patient.

The system is suitable for adults. Its results are not intended to be used on a standalone basis for clinical decision making or otherwise preclude clinical assessment of any disease.

6. COMPARAISON OF TECHNOLOGICAL CHARACTERISTICS

	NEW DEVICE PRAEVAorta® 2 Nurea	PRIMARY PREDICATE CT Cardiomegaly Innolitics K232613	Substantially Equivalent
Regulatory number	21 CFR 892.2050	21 CFR 892.2050	Same
Regulatory class	Class II	Class II	Same
Product code	QIH	QIH	Same
Device property	SaMD	SaMD	Same
Indication for use	PRAEVAorta®2 is a software intended to be run on its own or as part of another medical device to automatically calculate maximum diameters of anatomical zones from a DICOM CT image containing blood vessels PRAEVAorta2 is designed to measure the maximal transverse diameter of vessel and determine the maximal general diameter using a non-adaptative machine learning algorithm Intended users of the software are aimed to the clinical specialist, physicians or other licensed practitioners in healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services. Any results obtained from the software by an intended user other than a physician must be validated by the physician responsible of the patient. The system is suitable for adults. Its results are not intended to be used on a standalone basis for clinical decision making or otherwise preclude clinical assessment of any disease	CT Cardiomegaly is software intended to be run on its own or as part of another medical device to automatically calculate linear and area based cardiothoracic ration (CTR) from a CT image containing the heart. CT Cardiomegaly is designed to measure the maximal transverse diameter of heart and maximal inner transverse diameter of thoracic cavity and calculate the CTR from an axial CT slice containing the heart using a non-adaptative machine learning algorithm. Intended users of the software are aimed to the physicians or other licensed practitioners in the healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services. The system is suitable for adults and transitional adolescents (18 to 21 years old but treated as an adult). Its results are not intended to be used on a stand-alone basis for clinical decision making or otherwise preclude clinical assessment of any disease.	Equivalent Indication for use of the two devices are analyzing CT scan images. Both the subject device and the primary predicate are using non adaptative machine learning algorithms. An observed difference between the subject device and the predicate is the anatomical zone analyzed in CT scan. The primary predicate is assessing the heart while the subject device is assessing arteries . However, these differences in technological characteristics do not affect safety and effectiveness of the device and have been supported with verification and validation testing.
Input	CT scan images	CT scan images	Same

	NEW DEVICE PRAEVAorta® 2 Nurea	PRIMARY PREDICATE CT Cardiomegaly Innolitics K232613	Substantially Equivalent
Output files	- PDF, JSON and DICOM SC report - DICOM GSPS	- PDF and JSON report	Equivalent The subject device proposed the same storage format as the primary predicate. However, it is also proposing two additional formats, "DICOM SC report" and "DICOM GSPS" This difference in technological characteristics does not affect safety and effectiveness of the device and has been supported with verification and validation testing.
Output measurements	- Maximal transverse diameter of vessels (aorta and iliac arteries) - Linear measurements (diameters) - Various visualization techniques: 2D/3D	- Linear and area based cardiothoracic ratio - Maximal transverse diameter of the heart - Maximal inner transverse diameter of thoracic cavity	Equivalent to the predicate. The subject device is realizing the similar measurements as the primary device. The main difference between the primary predicate and the subject device is the body part assessed. However, these differences in technological characteristics do not affect safety and effectiveness of the device and have been supported with verification and validation testing.
Report Structure	Report will be output in the PDF and JSON file, and DICOM SC report which is structured with following information: - Maximum orthogonal diameter of anatomical zones - Patient information - Reference value(s)	Report will be output in the PDF and JSON file format which is structured with following information: - CTR (both linear and area-based) - Patient information - Reference value(s)	Equivalent Both devices generate a reports with a final output (Maximal Orthogonal diameter or CTR), which is used to support medical diagnosis for a specific clinical condition and includes patient information.

	NEW DEVICE PRAEVAorta® 2 Nurea	PRIMARY PREDICATE CT Cardiomegaly Innolitics K232613	Substantially Equivalent
Intended users	- Physicians or other licensed practitioners in healthcare institutions - Clinical specialists with results validated by a physician	Physician or other licensed practitioners in the healthcare institutions	Equivalent The subject device is also intended to be used by clinical specialist, the results being validated by the doctor in charge.
Target population	- Adults	Adults and transitional adolescents (18 to 21 years old but treated as an adult)	Equivalent. The subject device is more restrictive as the primary predicate. These differences in technological characteristics do not affect safety and effectiveness of the device have been supported with verification and validation testing.
Location of anatomical structures	- Thoraco-abdominal-pelvis	Chest	The primary predicate is more restrictive as the new device. However these differences are supported with a performance bench test.
Imaging modality	- Computed Tomography (CT)	Computed Tomography (CT)	Same
Intended use environment	- Healthcare institutions (clinics, hospitals, healthcare facilities, residential care facilities and long-term care services) - Healthcare company realizing sizing assessment of vessels)	Healthcare institutions (clinics, hospitals, healthcare facilities, residential care facilities and long-term care services)	The subject device is usable by healthcare company realizing sizing assessment vessels while the primary predicate is not. However, these differences in technological characteristics do not affect the safety and effectiveness of the device and have been supported with verification and validation testing
Software device that operatures on off-the-shelf hardware	Yes	Yes	Same

	NEW DEVICE PRAEVAorta® 2 Nurea	PRIMARY PREDICATE CT Cardiomegaly Innolitics K232613	Substantially Equivalent
Software device uses software algorithms for image	Yes	Yes	Same
Diameter measurement	Yes, automated	Yes, automated	Same
Storage	Saved in PDF, JSON and DICOM SC format, DICOM GSPS	Saved in JSON and PDF file format	The subject device proposed the same storage format as the primary predicate and one format in common with the secondary predicate. However, it is also proposing an additional format "DICOM GSPS". This difference in technological characteristics does not affect safety and effectiveness of the device and have been supported with verification and validation testing
Software requirement	- Ubuntu - Docker	- Ubuntu 20.04.5 LTS (provided as a docker container) - Docker 23.0.1 or above	Equivalent
Algorithm type	Machine learning based algorithm (non-adaptative)	- Machine learning based algorithm (non-adaptative)	Same
Input of patient data	Command line interface (API)	Command line interface (API)	Same
Image assessment	- Linear (diameters) measurements - Automatic segmentation and quantitative analysis - Segmentation and analysis or aortic and iliac arteries	- Linear (diameter, ratio) - Area based ratio - Automatic segmentation and measurements	Equivalent. The subject device is more restrictive than the predicate. This difference in technological characteristics do not affect safety and effectiveness of the device and have been supported with verification and validation testing

7. PERFORMANCE DATA

7.1. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Device Software Functions".

The software verification and validation testing verified that the design requirements were successfully met. The Intended use and user needs were successfully validated.

These tests verified that the design requirements were met. Intended use and user requirements have been successfully validated. As the intended use, functionality and performance of PRAEVAorta®2 and predicate device are equivalent and the result of performance testing is evidence that PRAEVAorta® 2 performs in an equivalence manner to CT Cardiomegaly.

The following FDA recognized performance standards and guidance were performed in evaluating the functionality of PRAEVAorta® 2:

- 21 CFR Part 860 – Medical Device Classification Regulation
- 21 CFR Part 820 – Quality System Regulation (QSR)
- FDA SaMD Guidance – Software as a Medical Device : FDA Guidance
- FDA Validation Guidance – General Principles of Software Validation
- IEC 62304 : 2015 – Medical Device Software – Software Life Cycle Processes
- IEC 82304 : 2016 – Health Software – General Requirements for Product Safety
- ISO 13485 : 2016 – Medial Devices – Quality Management Systems Requirements
- ISO 14971 : 2019 – Medical Devices – Application of Risk Management to Medical Devices
- IEC 62366 : 2015 – Medical Devices – Application of Usability Engineering to Medical Devices
- ISO 20417 : 2021 – Medical Devices – Information to be supplied by the manufacturer
- ISO 15223-1:2021 – Medical Devices – Symbols to Be Used with Medical Device Label, Labeling and information to be supplied

The following functional performance testing has been carried out to demonstrate that the device performs as intended:

- for automatic segmentation and geometric analysis of vessels
- to measure the maximal transverse diameter of vessels and determine the maximal general diameter using a non-adaptative machine learning algorithm
- Data security

7.2. Performance assessment

A technical performance assessment of PRAEVAorta® 2 was conducted to assess measurement accuracy, in comparison with manual measurements performed by qualified medical professionals (Ground Truth). The evaluated measurements are orthogonal diameters of the aorta. The critical variable was the total maximum orthogonal aorta diameter.

a) Reference standard.

The reference group consisted of four experts, all vascular surgeons with at least five years of clinical experience in vascular diseases following board certification. All experts had no financial conflicts of interest and received adequate training from NUREA.
The manual measurements performed by these healthcare professionals are referred to as the "ground truth."
The measurements performed by these professionals showed no discrepancy greater than 5 mm at the end of the collected data process.

b) Training and testing dataset

A technical performance assessment was performed for PRAEVAorta®2 to validate its accuracy against measurements provided by the Ground Truth using manual measurement tools.

The testing dataset included 159 unique cases from United States, France and Canada. Information collected on the dataset included patient demographics (sex, aneurysm type), imaging characteristics (geographic origin, slice thickness, scanner manufacturer and model, presence or absence of contrast) and clinical management details, including the presence, absence and types of stent graft for postoperative cases. Images were representative of numerous scanner manufacturers (e.g., GE Medical System, Siemens, Philips, Toshiba).

The dataset included both contrast-enhanced and non-contrast-enhanced CT scans from the United States (81 CT scans), supplemented with scans from France (40 CT Scans) and Canada (38 CT Scans). The selected CT scans were not used for AI training.

The dataset included of 159 patients aged over 18 years, including 130 males, 28 females, and one patient of unknown sex. It comprised 95 preoperative and 64 postoperative CT scans, among which 62 with an aortic stent graft.

c) Testing performance result

The acceptance criteria are the mean absolute error for the total maximum orthogonal aorta diameter between PRAEVAorta®2 and Ground Truth must be less than or equal to 5 mm and in at least 96% of

cases. The correlation coefficient for the total maximum orthogonal aorta diameter between PRAEVAorta®2 and Ground Truth must be at least greater than 0.90 (defined as a very strong correlation).

Observed performance showed that the mean absolute error between the ground truth measurements and PRAEVAorta®2 measurements for total maximum orthogonal diameter was 2.04 mm (95% CI: [1.75 mm; 2.34 mm]), with 96.9% of values within a ≤ 5 mm limit. The primary performance validation criterion is therefore considered met.

The evaluation included a Bland-Altman analysis with a detailed examination of error and bias. The mean difference (bias) between the ground truth and PRAEVAorta®2 for the total maximum orthogonal diameter was -0.75 mm (95% CI: [-1.17 mm; -0.33 mm;]), with 96,9% of values within the 95% limit of agreement, ranged from –6.01 mm to +4.51 mm. This result, close to zero, suggests strong consistency between ground truth and PRAEVAorta®2.

The Pearson correlation coefficient between the ground truth and PRAEVAorta®2 measurements for total maximum orthogonal diameter was 0.97, confirming that the primary performance validation criterion is achieved.

A summary table of results is provided below:

Variable	Mean absolute error			Bland Altman		Pearson coefficient	
	MAE [CI 95% -; CI 95% +]	Target	Percentage ≤5mm	Bias	95% limit of agreement	Correlation coefficient	Target
Total maximum orthogonal diameter	2.04 mm (95% CI: [1.75 mm; 2.34 mm])	≤ 5 mm	96.9 %	-0.75 mm (95% CI: [-1.17 mm; -0.33 mm])	96.9 %	0.97	> 0.90

The performance test shows acceptable performances of the software on secondary variables.

8. CONCLUSION

PRAEVAorta®2 is substantially equivalent to the predicate device identified CT Cardiomegaly (K232613) and offers strong clinical value through high measurement accuracy and reliability.
PRAEVAorta®2 has similar indications for use and technological characteristics to those of the previously cleared predicate device.

The minor differences between the technological characteristics of PRAEVAorta®2 and CT Cardiomegaly do not raise new questions of safety or effectiveness. Performance tests have been carried out and successfully confirm the performance of the subject device.
Consequently, PRAEVAorta®2 is substantially equivalent to the predicate CT Cardiomegaly.