February 16, 2021

GE Medical Systems SCS
℅ Elizabeth Mathew
Senior Regulatory Affairs Manager
283 rue de la Miniere
Buc, Yvelines 78530
FRANCE

Re: K200626
Trade/Device Name: VesselIQ Xpress
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: January 13, 2021
Received: January 14, 2021

Dear Elizabeth Mathew:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200626

Device Name

VesselIQ Xpress

Indications for Use *(Describe)*

VesselIQ Xpress is an optional, non-invasive, optimized, post-processing application intended to provide images and tools to analyze vascular anatomy and pathology, aiding physicians in diagnosis and determination of treatment paths, from a set of Computed Tomography (CT) Angiographic images.

VesselIQ Xpress is an option for the Advantage Workstation (AW) platform, CT Scanner, and/or PACS, which can be used in the analysis of 2D and 3D CT Angiography images/data for the purpose of cardiovascular and vascular disease assessment. This software-only device is designed to support physician assessment for a wide variety of clinical uses such as stenosis analysis, pre/post stent planning, pre/post valve replacement planning, and directional vessel tortuosity visualization.

VesselIQ Xpress' automatic visualization tools provide users the capability to segment bony structures for accurate identification of the vessels. Additional tools enable analysis of the vascular anatomy including the aorta, valves, and branching vessels for: anatomical sizing; density and volume analysis of segmented vasculature and calcified / non-calcified plaque; and measurements of abnormalities.

The TAVI Analysis option for VesselIQ Xpress is a planning tool used for Trans Aortic Valve Implantation (TAVI) procedures. It automatically segments the aorta and displays the aortic valve in multiple views for measurements of anatomic structures commonly needed for aortic annulus replacement planning. TAVI Analysis provides guided workflow and semi-automated tools to aid in evaluation of appropriate access pathways for interventional procedure planning.

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 or 510(k) Statement

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	February 15, 2021
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager Tel: 262-424-7774 Email: Elizabeth.Mathew@ge.com
Secondary Contact Person:	John Jaeckle Chief regulatory Affairs Strategist Tel: 262-424-9547 Email: John.Jaeckle@ge.com
Device Trade Name:	VesselIQ Xpress
Common/Usual Name:	VesselIQ, AVA
Proposed Device: Primary Regulation Number: Primary Product Code: Secondary Product Code: Classification Panel: Regulatory Class:	 21CFR 892.1750, Computed Tomography X-Ray System JAK LLZ Radiology Class II
Predicate Device 1: 510(k) number Regulation Number: Product Code: Classification Panel: Regulatory Class: Manufacturer:	Advanced Vessel Analysis II K060779, cleared on April 5, 2006 21CFR 892.1750, Computed Tomography X-Ray System JAK Radiology Class II GE Healthcare (GE Medical Systems)

Device Description:

VesselIQ Xpress:

CT Advanced vessel analysis is a post processing analysis software package designed to assist physicians in the evaluation and assessment of vascular anatomy.

VesselIQ Xpress is a software post-processing package for the Advantage. Workstation (AW) platform, CT scanners and PACS reading stations. It is an additional tool for the analysis of 2D & 3D CT angiographic images. It provides and facilitates generating a variety of displays, measurements and batch filming/archive features to study user-selected vasculature which include but are not limited to stenosis analysis, thrombus, pre/post stent planning procedures, pre/post valve planning procedures and directional vessel tortuosity visualization.

TAVI Analysis Option in VesselIQ Xpress:

TAVI Analysis is a post-processing software package for the Advantage Workstation (AW) and AW Server platforms. It is a planning tool used for Trans Aortic Valve Implantation (TAVI) procedures. It automatically segments the aorta and displays the aortic valve in multiple views for quick and easy measurements of anatomic structures commonly needed for aortic annulus replacement planning. TAVI Analysis provides guided workflow and semi-automated tools to help evaluate appropriate access pathways and can communicate directly with the interventional suite.

FlightPlan for EVAR Option in VesselIQ Xpress:

FlightPlan for EVAR is a post-processing software package for the Advantage Workstation (AW) and AW Server platforms. It is a planning tool used for Endovascular Aneurysm Repair (EVAR) procedures. The software helps to visualize the vascular anatomy, perform key anatomical measurements, choose the treatment strategy, size the endograft and save key information that can be used during the intervention.

Intended Use:

VesselIQ Xpress is a non-invasive, optimized, post-processing application intended to provide images and tools to analyze vascular anatomy and pathology aiding physicians in assessment, diagnosis, and determination of treatment paths for cardiovascular and vascular disease, from a set of Computed Tomography Angiographic images.

Indications for Use:

VesselIQ Xpress is an optional, non-invasive, optimized, post-processing application intended to provide images and tools to analyze vascular anatomy and pathology, aiding physicians in diagnosis and determination of treatment paths, from a set of Computed Tomography (CT) Angiographic images.

VesselIQ Xpress is an option for the Advantage Workstation (AW) platform, CT Scanner, and/or PACS, which can be used in the analysis of 2D and 3D CT Angiography images/data for the purpose of cardiovascular and vascular disease assessment. This software-only device is designed to support physician assessment for a wide variety of clinical uses such as stenosis analysis, pre/post stent planning, pre/post valve replacement planning, and directional vessel tortuosity visualization.

VesselIQ Xpress' automatic visualization tools provide users the capability to segment bony structures for accurate identification of the vessels. Additional tools enable analysis of the vascular anatomy including the aorta, valves, and branching vessels for: anatomical sizing; density and volume analysis of segmented vasculature and calcified / non-calcified plaque; and measurements of abnormalities

The TAVI Analysis option for VesselIQ Xpress is a planning tool used for Trans Aortic Valve Implantation (TAVI) procedures. It automatically segments the aorta and displays the aortic valve in multiple views for measurements of anatomic structures commonly needed for aortic annulus replacement planning. TAVI Analysis provides guided workflow and semi-automated tools to aid in evaluation of appropriate access pathways for interventional procedure planning.

Technology:

The VesselIQ Xpress software employs the same fundamental scientific technology as its predicate device.

Comparison:

The table below summarizes the feature/technological comparison between the predicate device and the proposed device:

Specification	**Predicate Advanced Vessel Analysis II** (K060779)	**Proposed VesselIQ Xpress**	**Comparison**
Aorta Segmentation	Yes	Yes	Predicate device (AVA II) segmented the aorta after user deposited points to identify the desired vasculature. In proposed device, the application can automatically initiate the aorta segmentation and display the results in a volume rendering model.
Aortic Valve Plane Detection	No	Yes	Predicate device provided users with oblique reformat tools to manually orientate anatomy into off access orientations. Proposed device offers an initial attempt to orientating images to the aortic annular plane and then prompts users to precisely refine the auto-initiated orientation. Additionally, the identical oblique tool that was present in the predicate device is also available for users in the proposed device to use as a way to precisely refine the orientation to the annular plane.
Aorta Angulation	No	Yes	Aorta angles, also referred to as cath angles provide the perpendicular angles to the aortic annulus plane. In the proposed device, these perpendicular values are graphically represented on the S-curve and users are able to interactively move the model by navigating along the S-Curve. Additionally, users can display the angle value between the annulus plane and the horizontal plane.
Aortic Measurements	Yes	Yes	Predicate device, provided individual tools for distance measurements, free hand contouring and spline contouring which were available for contouring of any anatomy. Proposed device offers a guided workflow, stepping through the typical pre-procedure measurements recommended for TAVR work-ups and provides semi-automation for a pre-defined list of measurements. All measurements are based

			on user inputs for annular plane and annular contour.
Calcification Volume	No	Yes	In the predicate device the calcium volume measurements were done manually by using standard Volume Viewer tools. In the proposed device, calcification quantification with automated calcification segmentation is provided.
Aorta Analysis	Yes	Yes	Aorta vessel tracking is present in the predicate device. The advancement of the aorta vessel tracking in the proposed device is the automatic point deposit for the start and end locations for the centerline to be displayed automatically. Results are displayed and the user can modify immediately if not satisfied.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The subject device VesselIQ Xpress was designed under the Quality System Regulations of 21CFR 820 and ISO 13485. It has successfully completed the design control testing per our quality system with no unexpected test results observed. The device modifications to VesselIQ Xpress product as compared to the predicate device do not change intended use from the predicate.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification, validation)
- Safety testing (Verification)

All the testing and results did not raise new questions of safety and effectiveness from those associated with predicate device and demonstrated that VesselIQ Xpress performs substantially equivalent to the predicate device.

The substantial equivalence determination is also based on the software documentation for a MODERATE level of concern device.

Summary of Clinical Testing

An independent clinical study of 80 patients that underwent successful TAVI procedure with pre procedural CT exams were retrospectively selected for evaluation by three qualified physicians.

The study compared manual measurements by the predicate, which is routinely used during the institution's TAVI planning, and semi-automated measurements by TAVI software for aortic annulus assessment in terms of measurement agreement and time spent on tasks among different operators with different experience in cardiovascular CT.

High correlations were found between manual and TAVI software aided measurements for aortic annulus area, perimeter, minimum diameter and maximum diameter in comparison with standard measurements for the 3 readers.

The result also shows agreement when taking the mean values of all three readers and comparing to the reference standard, demonstrating equivalent performance of the TAVI software to the standard manual measurements.

Substantial Equivalence Conclusion:

The device modifications to VesselIQ Xpress product as compared to the predicate device do not change intended use from the predicate.

VesselIQ Xpress was developed under GE Healthcare's quality system. The subject device's design, verification & validation, and risk management processes did not identify any additional hazards, unexpected results, or adverse effects stemming from the changes to the predicate. Design verification and validation, including clinical testing provided in this submission demonstrates that VesselIQ Xpress is substantially equivalent and hence as safe and as effective as the legally marketed predicate device.