August 8, 2023

Gentuity, LLC
Padmini Gagnon
Regulatory Affairs Manager
142 North Road, Suite G
Sudbury, Massachusetts 01776

Re: K230620
Trade/Device Name: Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, NQQ
Dated: March 31, 2023
Received: April 3, 2023

Dear Padmini Gagnon:

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,

Aneesh S. Deoras -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K230620

Device Name
The Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter

Indications for Use *(Describe)*
The Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

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

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Gentuity, LLC
142 North Road, Suite G
Sudbury, MA 01776

1.2 Official Correspondent

Padmini Gagnon
Gentuity, LLC
142 North Road, Suite G
Sudbury, MA 01776
Email: pgagnon@gentuity.com
Phone (508) 425-1560

1.3 Date of Preparation

June 28, 2023

2. NAME OF THE DEVICE

2.1 Trade/Proprietary Name

Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter

2.2 Common/Usual Name

Optical Coherence Tomography Imaging System
Optical Coherence Tomography Intravascular Catheter

2.3 510(k) number - K230620

2.4 Classification Information

Classification Name:	Optical Coherence Tomography Imaging System
Classification Regulation:	21 CFR 892.1560
Class:	II
Product Code:	NQQ
Panel:	Cardiovascular

Classification Name:	Diagnostic Intravascular Catheter
Classification Regulation:	21 CFR 870.1200
Class:	II
Product Code:	DQO
Panel:	Cardiovascular

3. PREDICATE DEVICE

Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter, K192922

4. REFERENCE DEVICE

Abbott Medical's "OPTIS™ Mobile Next Imaging System, OPTIS™ Integrated Next Imaging System with Ultreon™ Software 1.0". This OCT device has been cleared under K210458 and shares the same intended use as the Gentuity device as well as similar software features.

5. DESCRIPTION OF THE DEVICE

The Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter (herein the "Gentuity Imaging System") provides images of the coronary arteries in patients who are candidates for transluminal interventional procedures. The system utilizes fiber-optic technology to deliver near-infrared light and receive light reflected from coronary tissue to produce high resolution, real-time images.

The Gentuity Imaging System consists of the following components:

1. **The Gentuity Imaging Console:** A mobile system that houses the Optical Engine, the Computer and application software, and the Probe Interface Module (PIM). It also includes two monitors, keyboard, mouse, and cord storage as well as external interfaces to the system. The PIM provides the interconnection between the Gentuity Imaging System and the Vis-Rx Catheter.

2. **Vis-Rx Micro-Imaging Catheter:** The Vis-Rx Catheter is a sterile, single-use catheter that consists of an external sheath and an optical imaging core. The external sheath facilitates placement of the device into the coronary artery and houses the optical imaging core. An optical fiber and lens assembly rotates inside the optical imaging core. The optical fiber and lens deliver near-infrared light to the tissue and receive reflected light. The Vis-Rx catheter is a rapid exchange design, compatible with an 0.014" guidewire. The catheter attaches to the PIM, which is mounted outside the sterile field on the table bed rail. A sterile 3 ml purge syringe is provided with the Vis-Rx catheter.

3. **Optional Gentuity Review Station:** The Gentuity Review Station (GRS) is an optional stand-alone computer with the Gentuity application software that provides analysis and review capabilities similar to what may be performed on the Gentuity Console. The GRS allows physicians to review images for research, presentation and publication preparation outside the catheterization lab without the Gentuity Console.

6. INDICATIONS FOR USE

The Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

A comparison of the technological features between the proposed modified Gentuity device, which includes software modifications and new device features, and its predicate device is shown in Table 1 below.

Table 1. Comparison Table

Description	**Gentuity Imaging System** (K192922)	**Gentuity Imaging System** (Subject Device) K230620
Mode of Operation	Computer controlled swept-source (rapidly tunable laser) transmitting near-infrared light delivered through an Imaging Core housed within an External Catheter Sheath. Image acquisition (imaging core rotation and pullback) driven by system-catheter interconnection (PIM) and synchronized with contrast injection. Reflected light is collected, returned, and processed by the system hardware and software to construct an OCT image.	Same
Intended Use	Intravascular image in the coronary arteries	Same

Description	Gentuity Imaging System (K192922)	Gentuity Imaging System (Subject Device) K230620
Indications for use	The Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.	Same
Classification	21 CFR 892.1560 NQQ System, Imaging OCT	Same
Optical Engine	Swept-source laser	Same
Computer	A host computer with embedded application software	Same
Interconnection between system and catheter	Probe Interface Module (PIM)	Same
Console	A mobile console with monitors, keyboard and mouse, housing the optical engine and host computer, and connected to the PIM via an electro-optical umbilical cord.	Same
System Optical Specifications		
Swept-source laser	Class 1	Same
Center wavelength	1310 nm (nominal)	Same
Aiming beam laser	Class 1	Same
Wavelength	650 nm (nominal)	Same
Pullback Parameters		
Pullback Range	Variable up to 100 mm	Same
Pullback Rate	Variable up to 100 mm/sec	Same
General Scan Parameters		
Scan Range	7.6 mm (in contrast)	8.93 mm (in contrast)
Axial Resolution	Less than 20 µm in tissue	Same
Optical Sensitivity	≥ 90 dB	Same
A-line rate	200 kHz	Same

Description	Gentuity Imaging System (K192922)	Gentuity Imaging System (Subject Device) K230620
Frame Rate	250 frames per second (Hz)	Same
Image Display	Cross Section L-mode Lumen profile display 3D Angio sync	Same
Software Features	Automatic lumen detection Automatic lumen measurements Automatic MLA identification User generated length, area measurements Text annotations Zoom	Same
Software Features (Stent Expansion Visualization Tool)	Not available	Stent Expansion View Mode Longitudinal Zoom & Zoom Indicator AI to identify B-Mode with Stent & Guide Catheter Training Mode Image Display Speed Optimization Angle measurement tool

7.1 Similarities and Differences in Technology Comparison

The modified software and its features are substantially equivalent to the Gentuity Imaging System in terms of product intended use, design, mode of action, materials of construction, operational and technological features, hardware, firmware components, clinical use, and target population.

Both the proposed device software and the predicate Gentuity Imaging System software perform OCT Imaging acquisition using OCT software. The Gentuity console employs a graphical user interface (GUI) and software control to obtain and display Optical Coherence Tomography (OCT) images. The Gentuity System provides angiographic inputs and outputs allowing shared display of OCT and angiographic images. Components are housed in a mobile cart and include a PIM which provides the interconnection between the "Gentuity System" and the "Vis-Rx Catheter" that emit near-infrared light to produce high-resolution real-time images. These features remain the same and are unaffected by the addition of the new software features.

The device modifications represent an incremental improvement to the predicate device in terms of adding the new software features:

- Stent Expansion View Mode
- Longitudinal Zoom & Zoom Indicator
- AI to identify B-Mode with Stent & Guide Catheter
- Training Mode
- Image Display Speed Optimization
- Angle measurement tool

8. PERFORMANCE TESTING

The modified software has been developed and tested in compliance with IEC 62304: 2015. Software verification and validation activities as well as design validation were performed to evaluate the proposed device software modifications.

Software Verification testing has been conducted to confirm that the device modifications meet its product specifications and that these modifications do not raise any new issues of safety and effectiveness. Additionally, design validation against the user needs was conducted using the new features of the user interface. Software verification and validation was conducted to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met these requirements and that the software is determined to be safe and effective and is substantially equivalent to the predicate Gentuity HF-OCT Imaging System.

HF-OCT images used as the AI training and test data sets included clinical data acquired with the Gentuity HF-OCT Imaging System and Vis-Rx catheters. The study population was based on the 510(k) cleared Gentuity device indications for use statement and its product labeling. The intent-to-treat population included participants that were already scheduled for a visit to the catheterization laboratory and were candidates for transluminal interventional procedures.

Patient population included the following:

Training			Test		
Age			Age		
Range	(N)	(%)	Range	(N)	(%)
<25	0	0	<25	0	0
26-50	3	15	26-50	1	4
51-75	12	60	51-75	17	68
76-100	5	25	76-100	7	28
Sex			Sex		
	(N)	(%)		(N)	(%)
Male	15	75	Male	15	60
Female	5	25	Female	10	40
BMI			BMI		
Range	(N)	(%)	Range	(N)	(%)
<25	1	5	<25	3	12
25-40	17	85	25-40	20	80
>40	2	10	>40	2	8

9. CONCLUSIONS

The information presented in these 510(k) submissions demonstrates that the modified subject device software and its features are substantially equivalent to the predicate device Gentuity HF-OCT Imaging System software.