January 31, 2025

Gentuity, LLC
Edwin Rule
Director, Global Regulatory Affairs
142 North Road
Suite G
Sudbury, Massachusetts 01776

Re: K242966
Trade/Device Name: Gentuity® HF-OCT Imaging System with Vis-Rx Prime® Micro-Imaging Catheter
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: NQQ, DQO
Dated: January 3, 2025
Received: January 3, 2025

Dear Edwin Rule:

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,

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)*
K242966

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

Indications for Use *(Describe)*
The Gentuity® HF-OCT Imaging System with Vis-Rx® Prime 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 Prime Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Prime Micro-Imaging Catheter is also intended for use prior to or following transluminal interventional procedures. The Vis-Rx Prime 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.

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.

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"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."

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

Edwin Rule
142 North Road
Suite G
Sudbury, MA 01776
erule@gentuity.com

1.3 Date of Preparation

September 20, 2024

2. NAME OF THE DEVICE

2.1 Trade/Proprietary Name

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

2.2 Common/Usual Name

Optical Coherence Tomography Imaging System
Optical Coherence Tomography Intravascular Catheter

2.3 510(k) Number

K242966

2.4 Classification Information

Classification Name:	Ultrasonic Pulsed Echo Imaging System
Classification Regulation:	21 CFR 892.1560
Class:	II
Product Code:	NQQ
Panel:	General Surgical

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 (K242239).

4. DESCRIPTION OF THE DEVICE

The Gentuity® HF-OCT 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 HF-OCT 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® Prime Micro-Imaging Catheter.

2. **Vis-Rx Prime Micro-Imaging Catheter:** The Vis-Rx Prime Micro-Imaging 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 Prime Micro-Imaging 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 Prime Micro-Imaging 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.

5. INDICATIONS FOR USE

The Gentuity® HF-OCT Imaging System with Vis-Rx® Prime 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 Prime Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Prime Micro-Imaging Catheter is also intended for use prior to or following transluminal interventional procedures. The Vis-Rx Prime Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

6. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

There have been no changes to the Intended Use or to the Indications for Use of the device. The Vis-Rx Prime Micro-Imaging Catheter design seeks to accomplish the following:

- Materials changes (catheter)
- Minor design changes (catheter)
- Change packaging from a tray with a sealed lid inside a sealed pouch to a clamshell tray in a sealed pouch (catheter)
- Sterilization method change from e-beam to gamma irradiation (catheter)
- Resolve software anomalies (console)

7. PERFORMANCE TESTING

Performance testing to support the review of the 510(k) Premarket Notification included bench and animal testing. The following performance data supported substantial equivalence.

Biocompatibility

The biocompatibility evaluation for the Gentuity® HF-OCT Imaging System with Vis-Rx® Prime Catheter was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogen Testing
- Hemocompatibility - Hemolysis
- Hemocompatibility – Partial Thromboplastin Time (PTT)
- Hemolysis – Complement Activation
- Thrombogenicity

The Vis-Rx Prime Micro-Imaging Catheter is considered an External Communicating Device: Circulating Blood, <24 hour contact. All biocompatibility validation results met applicable acceptance criteria.

Particulate and Coating Integrity

The external sheath of the Vis-Rx Prime Micro-Imaging Catheter has a hydrophilic coating applied to the distal segment. The coating integrity and particulate of the Vis-Rx Prime Micro-Imaging Catheter was categorized per FDA Guidance, Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (2010). Particulate and Coating Integrity was successfully characterized.

Sterilization Validation Testing

The Vis-Rx Prime Micro-Imaging Catheter is sterilized using Gamma irradiation. Sterilization Validation was performed in accordance with ISO 11137-1 and ISO 11137-2. All sterilization validation results met applicable acceptance criteria.

Animal Study

A GLP Animal Study was conducted in compliance with the FDA regulation, 21CFR Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies under Good Laboratory Practice Standards. The GLP Animal Study was successfully completed in compliance with the requirements of the GLP Nonclinical Laboratory Practice requirements.

8. CONCLUSIONS

The information presented in this 510(k) Premarket Notification demonstrates the Gentuity® HF-OCT Imaging System with Vis-Rx® Prime Micro-Imaging Catheter is substantially equivalent to the predicate device.