August 16, 2024

Gentuity, LLC
Sharon Timberlake
Vice President Clinical, Quality and Regulatory Affairs
142 North Road, Suite G
Sudbury, Massachusetts 01776

Re: K242239
Trade/Device Name: Gentuity® HF-OCT Imaging System with Vis-Rx® 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: July 29, 2024
Received: July 30, 2024

Dear Sharon Timberlake:

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.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242239

Device Name
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 also intended for use prior to or following transluminal interventional procedures. 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.

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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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

Sharon Timberlake
142 North Road
Suite G
Sudbury, MA 01776
stimberlake@gentuity.com

1.3 Date of Preparation

August 15, 2024

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

K242239

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:	Optical Coherence Tomography 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 (K230620).

4. DESCRIPTION OF THE DEVICE

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 Console 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.

5. 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 also intended for use prior to or following transluminal interventional procedures. The Vis-Rx 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 technological characteristics, sterilization method, device packaging, device materials and components of the proposed device being reviewed under

this 510(k) Premarket Notification. As a result, the proposed device is identical to the predicate device.

7. PERFORMANCE TESTING

No additional non-clinical and clinical performance testing was required to support review of this 510(k) Premarket Notification.

8. CONCLUSIONS

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