February 20, 2020

Gentuity, LLC
% Diane Horwitz
Regulatory Consultant
Mandell Horwitz Consultants LLC
5 Lake Como Ct.
Greenville, South Carolina 29609

Re: K192922
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: January 22, 2020
Received: January 22, 2020

Dear Diane Horwitz:

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,

Mark Fellman
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192922

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 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

Diane Horwitz, Ph.D., RAC
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Greenville, SC 29609
Telephone: 703.307.2921
Email: dmh@mandellhorwitzconsulting.com

1.3 Date of Preparation

February 19, 2020

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

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

2.1.2 Common/Usual Name

Optical Coherence Tomography Imaging System
Optical Coherence Tomography Intravascular Catheter

2.1.3 Classification Information

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

Reference Device:	
Classification Name:	Optical Coherence Tomography Intravascular Catheter
Classification Regulation:	21 CFR 870.1200
Class:	II
Product Code:	ORD
Panel:	Cardiovascular

3. PREDICATE DEVICES

ILUMIEN OPTIS™ Mobile System, Lightlab Imaging, Inc., K152120 (Primary Predicate)
Dragonfly™ OPTIS™ Imaging Catheter, Lightlab Imaging, Inc., K141453

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 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. INDICATION 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.

6. INTENDED USE COMPARED TO THE PREDICATES

The intended use for the Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter is the same as the predicate device. The statement is similar with changes to the scan range and imaging of the left main coronary artery. The devices share the same target patient population, the same users and conditions of use. Both devices are prescription only.

The increased scan range of the Gentuity System allows imaging of vessels up to 6 mm in diameter, which covers the expected diameter range of left main coronary arteries. This change does not introduce new issues of safety or effectiveness and was validated using bench and GLP animal testing.

Table 1. Intended Use / Indications for Use Comparison for the Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter Versus the Predicate

Subject Device Gentuity® Imaging System with Vis-Rx® Imaging Catheter	Primary Predicate ILUMIEN OPTIS™ Mobile System, K152120	Secondary Predicate Dragonfly™ OPTIS™ Imaging Catheter, K141453
21 CFR 892.1560 21 CFR 870.1200	21 CFR 892.1560	21 CFR 870.1200
System Imaging Optical Coherence Tomography (OCT), Diagnostic Intravascular Catheter	System Imaging Optical Coherence Tomography (OCT)	Diagnostic Intravascular Catheter
Procode: NQQ, DQO	NQQ	DQO
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.	The OPTIS™ Mobile System with Dragonfly™ DUO or Dragonfly™ OPTIS™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly™ DUO or Dragonfly™ OPTIS™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ DUO or Dragonfly™ OPTIS™ Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The OPTIS™ Mobile System will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.	The ILUMIEN OPTIS with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The ILUMIEN OPTIS will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATES

A comparison of the technological features between the Gentuity® Imaging System and the predicate is shown in **Table 2** below for the Gentuity Imaging Console and in **Table 3** for the Vis-Rx® Imaging Catheter.

Table 2. Technology Comparison for Gentuity Imaging Console Versus the OPTIS Predicate

Technological Characteristic	Subject Device Gentuity Imaging Console	Predicate OPTIS™ Mobile System, (K152120)	Same or Different Significance
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. Returned reflected light is processed by the system hardware and software to construct an OCT image.	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 (DOC) and synchronized with contrast injection. Returned reflected light is processed by the system hardware and software to construct an OCT image*	Same
System Components	A swept-source engine	A swept-source engine	Same
	A host computer with embedded application software	A host computer with embedded application software	Same
	Interconnection between system and catheter (PIM)	Interconnection between system and catheter (DOC)	Same
	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.	A mobile console with monitors, keyboard and mouse, housing the optical engine and host computer, and connected to the DOC via an electro-optical umbilical cord.	Same
Optical Parameters	Swept-source Center Wavelength: 1310 nm (nominal) Class 1	Swept-source Center Wavelength: 1305 nm (nominal) Class 1M	Same Similar; no optical safety precautions required
	Aiming beam - Visible laser diode Wavelength: 650 nm (nominal) Class 1	Aiming beam – Visible laser diode Wavelength: 670 nm (nominal) Class 1M	Same Similar; no optical safety precautions required
Image Display	Cross Section L-mode Profile display 3D Angio view	Cross Section L-mode Profile display 3D Angio coregistration	Same
Software Features	Automatic lumen detection Automatic lumen measurements User generated length, area measurements Text annotations Zoom	Automatic lumen detection Automatic lumen measurements User generated length, area measurements Text annotations Zoom	Same

Table 3. Technology Comparison for the Vis-Rx® Imaging Catheter Versus the Dragonfly Predicate

	Subject Device Vis-Rx® Imaging Catheter	Predicate Device Dragonfly OPTIS (K141453)	Same or Different Significance
Catheter Body External Sheath	1.8 Fr diameter	2.7 Fr diameter	Similar
Insertable Length	145 cm insertable length	135 cm insertable length	Similar
Tip	Minirail tip	Minirail tip	Same
Guide Catheter Compatibility	6 Fr	6 Fr	Same
Guidewire	0.014" guidewire compatible	0.014" guidewire compatible	Same
Connector	Connector Hub with optical and pullback connections	Connector Hub with optical and pullback connections	Same
Radiopaque Markers	Three markers	Three markers	Same
Purge	Saline purge of catheter lumen	Contrast purge of catheter lumen	Similar, using less contrast than the subject device.
RFID	Located in catheter connector and PIM	Located in catheter connector and DOC	Same
Sterile and Single Use	Yes	Yes	Same

7.1 Similarities and Differences in Technology Comparison

The Gentuity console and Vis-Rx® catheter are equivalent to the OPTIS Mobile System and Dragonfly OPTIS Imaging Catheter in terms of hardware, firmware components and operational use.

Console:
Components of both are housed in a mobile cart and include a PIM which provides the interconnection between the Imaging System and the optical imaging catheters that emit near-infrared light to produce high-resolution real-time images. Both the Gentuity console and the predicate device employ a graphical user interface (GUI) and software control to obtain and display Optical Coherence Tomography (OCT) images. Both systems provide angiographic inputs and outputs allowing shared display of OCT and angiographic images.

The Gentuity console represents an incremental improvement to the predicate device in terms of performance through the scanning laser, PIM design and technological characteristics. The improvements include the following: an increase in A-line rate, frame rate, image scan-range, pullback speed, and pullback length.

Ergonomic changes include a touch screen monitor enhancing input and display control for the non-sterile operator and bed rail mounting of the PIM supporting its placement outside of the sterile field and eliminating the need for bagging.

Catheter:
The Vis-Rx® catheter is equivalent to the predicate device in terms of functional design and operational use. They both are comprised of a rapid exchange catheter sheath and an internal imaging core comprising the rotating fiber optic and lens which emits near infrared light to the tissue and receives reflected light. Like the predicate, catheters are connected to the Console via the

PIM which controls lens rotation and pullback. Both catheters are purged prior to use. In both the Vis-Rx and the predicate device emitted and returned reflected light are combined and processed by imaging system software to construct an OCT image.

The Vis-Rx catheter represents an incremental improvement to the predicate device in terms of performance without change to operational characteristics and fundamental technology. The improvements include the following: Smaller crossing profile (1.8 Fr); higher speed imaging (250 frames/second), and longer pullback (≤100 mm).

8. PERFORMANCE TESTING

The Gentuity® Imaging System has been tested and is in compliance with general safety requirements, IEC 60825-1:2nd Ed. 2007, IEC 60601-1-2 Ed.3 IEC 60601-1-2:2014, IEC 60601-1-6: 2010+ A1:2013, IEC 60601-2-18: 2009; Laser Safety EC 60825-1:2014 21 CFR, Subchapter J, parts 1040.10 and 1040.11

In addition to the electrical safety testing performed, Gentuity Imaging System and Gentuity Review Station software has been developed and tested in compliance with IEC 62304: 2006 and DICOM Standard: 2015b. 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.

Design verification and validation of the Gentuity Imaging System was performed in compliance with internal design control procedures comprised of bench testing, animal testing, third-party image quality assessment and summative usability testing to confirm device performance.

8.1 Bench testing: Gentuity performed a series of bench tests to demonstrate its system meets its performance specifications using finished, sterilized and preconditioned product. Comprehensive verification and validation activities were successfully completed, raising no new issues of safety or effectiveness. All testing passed the acceptance criteria.

Performance testing was conducted against known standards or the product specification and evaluated the following:

Console, software and PIM

- Scan range
- Axial resolution
- Optical Sensitivity
- A-line rate
- Dynamic range
- Frame rate
- Pullback rate and range
- Fiber Optic Rotary Joint (FORJ) Insertion loss
- FORJ Rotational uniformity
- FORJ Return loss.

Catheter:

- Visual & Dimensional Inspection
- Tensile Strength

- Leakage
- Corrosion
- Torque
- Particulates
- Coating characterization
- Lubricity/Friction
- Flexibility and Kink

Biological Safety Testing
The Vis-Rx was subjected to a series of biocompatibility tests in accordance with FDA guidance, using International Standard ISO 10993-1.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis (Direct and Indirect)
- Complement SC5b-9 and C3a
- In Vivo Thrombogenicity

Sterilization

Sterilization and sterilization validation were performed to ensure a SAL of 10^{-6}, according to international sterilization standards.

Packaging Validation and Shelf Life

Visual Inspection, Bubble Leak and Seal Strength testing was used to evaluate integrity of the packaging configuration. Testing was conducted after sterilization, environmental conditioning including aging, and simulated shipping and distribution.

<u>System: Console, SW, PIM, Catheter</u>

- Simulated Use in tortuous path model
- Automatic Flush Detection
- Lumen Segmentation
- NURD (Non-Uniform Rotational Distortion)
- Image Brightness
- Lateral Resolution
- Measurement Accuracy

8.2 Animal Testing: Gentuity conducted two animal studies to evaluate the safety and effectiveness of its system compared to the predicate system.

- **Safety:** The Gentuity System performed as intended and the histomorphology findings were similar between the two treatment groups (Gentuity System versus predicate system). Clinical usability assessment evaluating catheter handling, ease of use and radiopacity was also performed and found to be similar to the predicate.

- **Third-Party Image Quality Assessment:** Two independent end user reviewers viewed cross-sectional images extracted from pullbacks with Vis-Rx and with the predicate device. Each cross-sectional image was scored by each reviewer on 3 image quality attributes (image contrast, axial resolution and tissue depth penetration) and 3 image artifacts (seam-

line (heart-beat motion artifacts), NURD (rotational motion artifacts) and saturation (strong reflection artifacts). The results of this test conclude that the two systems provide substantially equivalent imaging quality.

8.3 Summative Usability Testing: Usability evaluation was conducted to establish that the Gentuity Imaging System meets the needs of the intended users to perform OCT imaging safely and effectively according to ANSI/AAMI/IEC 62366-1:2015.

The results of the performance testing conclude the Gentuity Imaging System with the Vis-Rx Catheter is substantially equivalent to the ILUMIEN OPTIS with Dragonfly OPTIS Imaging Catheter predicate device.

9. CONCLUSIONS

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