Visura Technologies, LLC
% Gina Correa
Valleygrey Enterprise
396 N. Whisman Rd.
Mountain View, California 94043

July 10, 2018

Re: K180911
Trade/Device Name: Visura Technologies TEECAD System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS, ITX
Dated: June 8, 2018
Received: June 11, 2018

Dear Gina Correa:

This letter corrects our substantially equivalent letter of June 20, 2018.

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

3.0 INDICATION FOR USE

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)*

Device Name
Transesophageal Echocardiogram Camera Assist Device (TEECAD) System

Indications for Use *(Describe)*
The TEECAD System is intended to provide visualization during the placement of a Transesophageal Echocardiogram (TEE) probe in adults. Do not use this system for any purpose other than the intended use.

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.

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

4.0 510(K) SUMMARY

510(k) Notification K_____

4.1 GENERAL INFORMATION

Applicant:

Visura Technologies, LLC
9337 Harding Avenue
Evanston, IL, 60203
U.S.A.
Phone: 630-487-0140

Contact Person:

Ms. Gina Correa, RAC
Visura Technologies, LLC - Regulatory Consultant
Phone: 414-975-0022
Email: Gina.correa@gmail.com

Date Prepared:

June 1st 2018

4.2 DEVICE INFORMATION

Trade Name:

Transesophageal Echocardiogram Camera Assist Device (TEECAD) System

Generic/Common Name:

Transesophageal Echocardiogram Visualization System

Classification:

21 CFR 876.1500, Endoscope and accessories, Class II

Product Codes:

FDS and ITX

PREDICATE DEVICE

Third Eye Panoramic Auxiliary Endoscopy System (K140595)

REFERENCE DEVICE

Philips EPIQ 5 Diagnostic Ultrasound System, EPIQ 7 Diagnostic Ultrasound System, Affiniti 30 Diagnostic Ultrasound System, Affiniti 50 Diagnostic Ultrasound System, Affiniti 70 Diagnostic Ultrasound System (K172607)

DEVICE DESCRIPTION

The Visura TEE Camera Assist Device (TEECAD) is an accessory that provides visualization for the physician during TEE probe placement. It consists of a very simple design that has two main components:

- Disposable Carrier - a single-use carrier with an integrated camera
- Viewing System - a physician interface display unit

The TEECAD System is not a diagnostic or therapeutic device. The TEECAD Disposable Carrier acts as an accessory that attaches to the commercially available Philips X7-2t TEE transducer probe and is removed once the probe reaches its target location in the patient's esophagus to allow for normal ultrasound imaging of the heart.

The TEECAD Disposable Carrier is a single use device, and is designed to be manufactured with commonly used medical device materials that are considered safe for body contact.

The Viewing System includes software that allows the operator to view the endoscopic images during TEE probe placement. The software is installed by the manufacturer and cannot be accessed, modified or installed by the user.

A diagram of the Visura TEECAD System is provided in Figure 4-1.

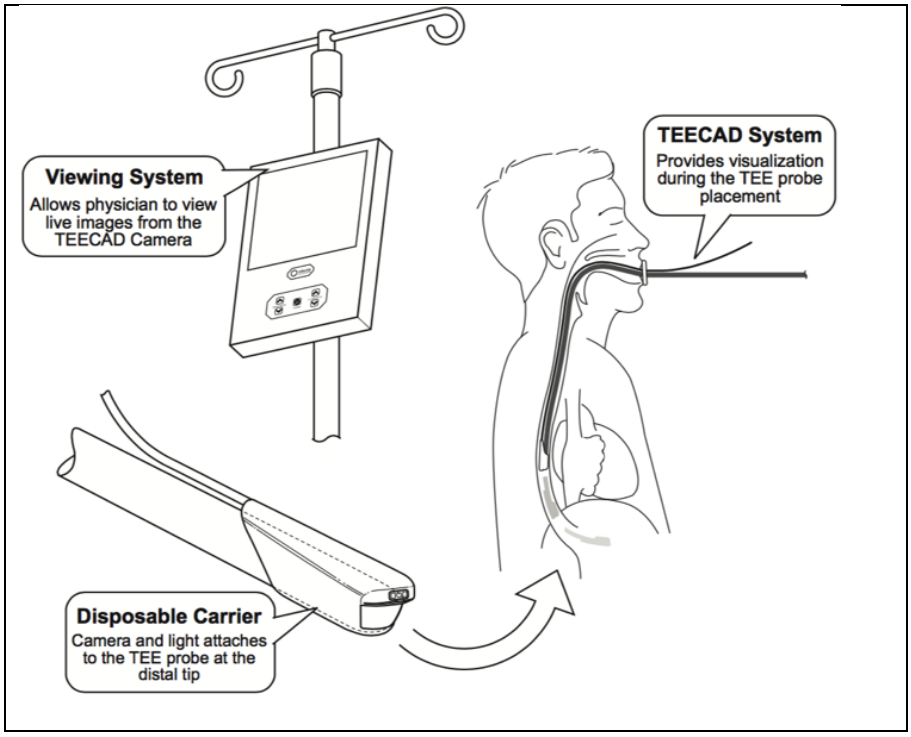

Figure 4-1: A diagram of the Visura TEECAD System

4.3 INDICATIONS FOR USE

The Visura Technologies TEECAD System is intended to provide visualization during the placement of a transesophageal echocardiogram probe in adults.

4.4 SUBSTANTIAL EQUIVALENCE

The Third Eye Panoramic Auxiliary Endoscopy System is listed as the predicate device for the TEECAD System.

The Third Eye Panoramic Device is indicated for use as an accessory to a conventional colonoscope to provide additional visualization and illumination of the colon, while the Visura TEECAD System is intended to provide visualization during the placement of a transesophageal echocardiogram probe in adults. Both the Visura TEECAD System and the Third Eye Panoramic System have the same overall functionality of providing improved visualization capability to an existing device (i.e. TEE probe, colonoscope). Both devices are very low risk accessories.

The main questions regarding safety and effectiveness with either accessory is its interaction with the parent device and its impact on the functionality of the parent device. These issues have been addressed via the verification and validation testing performed using the Visura TEECAD System.

Any differences between the TEECAD System and the predicate device do not alter the intended use of the TEECAD System. The safety and effectiveness of the TEECAD System has been demonstrated via the bench and animal testing described in Section 9.4 and Section 9.5.

The TEECAD System is only intended for us with the commercially available Philips X7-2t TEE transducer probe, where the TEECAD Carrier acts as an accessory that attaches to the transducer probe. The Philips ultrasound imaging system that supports the TEE probe (X7-2t) is listed as the reference device in this 510(k) submission.

4.5 NON-CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the TEECAD System to support a determination of substantial equivalence to the predicate device. The following non-clinical tests were conducted on the TEECAD System

- TEECAD Design Verification and Validation Studies
- Packaging Testing
- Biocompatibility Testing
- Cleaning Validation
- Software Verification and Validation

- Electrical safety, electromagnetic compatibility, and laser safety testing
- TEECAD System GLP Animal Safety and Performance Report

The collective results of the non-clinical tests demonstrate that the TEECAD System meets the established specifications necessary for consistent performance for its intended use.

4.6 CONCLUSION

The results of the nonclinical testing demonstrate that the TEECAD System is a safe and effective device. The risk assessment supported by the non-clinical testing demonstrates that the technological characteristics employed by the TEECAD System do not raise any new issues of safety or effectiveness. Therefore, the TEECAD System is substantially equivalent to the identified predicate device.