April 23, 2024

Provisio Medical, Inc.
℅ Zane Liu
Director, Regulatory Affairs
Veranex, Inc.
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K233948
Trade/Device Name: Provisio™ SLT IVUS™ System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, DQY, ITX, IYO
Dated: March 25, 2024
Received: March 25, 2024

Dear Zane Liu:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K233948

Device Name
Provisio™ SLT IVUS™ System

Indications for Use *(Describe)*
The Provisio™ SLT IVUS™ System is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature.

The Provisio™ SLT IVUS™ System is designed for use as an adjunct to conventional angiographic procedures to evaluate the vessel lumen and provide dimensional measurements.

The SLT IVUS™ Support Crossing Catheter also guides and supports a guidewire during access of the vasculature and provides a conduit for the delivery of saline solutions or radiopaque contrast agents.

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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| **510(k) #: K233948** | **510(k) Summary** | |
|---|---|---|
| **Contact Details** | | **21 CFR 807.92(a)(1)** |
| Applicant Name | Provisio Medical, Inc. | |
| Applicant Address | 10815 Rancho Bernardo Road<br>Suite 110<br>San Diego CA 92127<br>United States | |
| Applicant Contact Telephone | 858-524-3901 | |
| Applicant Contact | Mr. Robert Ashley | |
| Applicant Contact Email | rashley@provisiomedical.com | |
| **Device Name** | | **21 CFR 807.92(a)(2)** |
| Device Trade Name | Provisio™ SLT IVUS™ System | |
| Common Name | Diagnostic intravascular catheter | |
| Classification Name | Catheter, Ultrasound, Intravascular | |
| Regulation Number | 870.1200 | |
| Product Code | OBJ | |
| **Legally Marketed Predicate Devices** | | **21 CFR 807.92(a)(3)** |

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K200410 | Reconnaissance PV .018 OTW Digital IVUS Catheter | OBJ |
| K092396 | Quick-Cross Extreme Support Catheters | DQY |
| K173860 | s5/s5i/CORE/CORE Mobile Precision Guided Therapy System | IYO |

**Device Description Summary** **21 CFR 807.92(a)(4)**

The Provisio™ Sonic Lumen Tomography Intravascular Ultrasound ("SLT IVUS™") System is an IVUS system that utilizes A-mode ultrasound operation to evaluate the vessel lumen and provide dimensional measurements in real time. The Provisio™ SLT IVUS™ System comprises the SLT IVUS™ Support Crossing Catheter and the SLT IVUS™ P1 System, which includes the Pulser Receiver Unit, the Display Unit, and a Cart.

The SLT IVUS™ Support Crossing Catheters, provided sterile for single use, are over-the-wire intravascular ultrasound catheters with a digital ultrasound transducer array at the distal end. The information from the echoes is used to generate real-time dimensions and representations of the peripheral vessel's flow lumen. If required clinically, the SLT IVUS™ Support Crossing Catheter also functions as a support crossing catheter and may be used for the infusion of saline or radiopaque contrast agents.

The Provisio™ SLT IVUS™ System may be used in peripheral vascular procedures to generate real-time measurements of the vessel flow lumen dimensions, while also providing the functionality of the support crossing catheter in the same procedure. The cross-sectional parameters of diameter and area are displayed as numbers; additionally, the diameter measurement is graphically displayed as a representation of the flow lumen. The cross-sectional area measurements are displayed over time on a timeline display. As the catheter is moved by the operator through the vessel lumen, new cross-sectional measurements are obtained and displayed. Adjacent cross-sectional measurements can be compiled and displayed over a period of time to create an orthogonal graphical display of the vessel lumen (called RunView™).

The Provisio™ SLT IVUS™ System is intended to be used by physicians trained in peripheral interventional procedures as an adjunct to conventional angiographic procedures.

**Intended Use/Indications for Use** **21 CFR 807.92(a)(5)**

The Provisio™ SLT IVUS™ System is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature.

The Provisio™ SLT IVUS™ System is designed for use as an adjunct to conventional angiographic procedures to evaluate the vessel lumen and provide dimensional measurements.

The SLT IVUS™ Support Crossing Catheter also guides and supports a guidewire during access of the vasculature and provides a conduit for the delivery of saline solutions or radiopaque contrast agents.

**Indications for Use Comparison** **21 CFR 807.92(a)(5)**

The Provisio™ SLT IVUS™ System combines the features of an IVUS system (IVUS catheter and associated imaging system) and a support crossing catheter into a single product. As an IVUS System intended to support the evaluation of vascular morphology in blood vessels of the peripheral vasculature, the proposed device has the same intended use as the Philips Image Guided Therapy Corporation Reconnaissance PV .018 OTW Digital IVUS Catheter (K200410) primary predicate when used with the Volcano Corporation s5/s5i/CORE/CORE Mobile Precision Guided Therapy System (K173860) secondary predicate. As a support crossing catheter, the proposed device has the same intended use as the Spectranetics Corporation Quick-Cross® Extreme Support Catheters (K092396) secondary predicate. To reflect this combined functionality, the Indications for Use statement of the proposed device accordingly includes elements of the Indications for Use statements of each of the predicate devices, as it relates to their respective functionality.

**Technological Comparison** **21 CFR 807.92(a)(6)**

IVUS procedures, which are an adjunct to angiography procedures, are commonly used in the peripheral vasculature with a combination of devices: (1) IVUS catheter, (2) imaging system, and (3) support catheter often prior to, and following, the conduct of interventional and therapeutic procedures. The proposed device, and the predicate devices in combination, are similarly part of the complete procedural workflow in the peripheral vasculature for which IVUS is used. The proposed device is likewise similar in technology to the predicate devices.

There are differences between the proposed device and the predicate devices, primarily with respect to the proposed device's A-mode ultrasound operation and its associated display of ultrasound data. Specifically:

- When considered from the perspective of their roles as percutaneous catheters for their respective use within the peripheral vasculature, the proposed device is similar to the Reconnaissance and Quick-Cross predicate devices with respect to catheter form factor and design features, and any minor differences (e.g., crossing profile and other dimensional considerations) do not affect the intended use and clinical function, and as such, do not raise different questions of safety or effectiveness.
- With respect to use of ultrasound energy, the proposed device and the Reconnaissance primary predicate device both utilize acoustic energy that is sent toward and reflected by the vessel wall, and minor differences in ultrasound parameters do not affect the acoustic safety, basic safety, or essential performance requirements of the device as an IVUS System for use in peripheral vessels, and thus do not raise different questions of safety or effectiveness.
- With respect to their analysis approaches for vessel measurement, both the proposed device and the Volcano IVUS secondary predicate device analyze ultrasound signal reflections

(echoes) from the vessel wall to yield vascular morphology information. Both devices provide a visual representation of the vessel lumen and a similar range of numerical measurements. Furthermore, in both devices, the information is intended for interpretation by a trained physician in conjunction with, and/or as an adjunct to, angiographic findings. Thus, while analysis methodology (A-mode vs. B-mode) and display (spline and measurements vs. vessel image) are different between the proposed and predicate devices, they do not affect the type of information or their clinical use, and thus do not raise different questions of safety or effectiveness.

Therefore, Provisio Medical is of the opinion that these technological differences do not raise different questions of safety or effectiveness especially when viewed in relation to the workflow and key functionalities of the predicate devices.

**Non-Clinical and/or Clinical Tests Summary & Conclusions** **21 CFR 807.92(b)**

Non-Clinical Testing Summary

Provisio Medical has conducted all necessary testing to demonstrate that the proposed device meets all performance specifications necessary to achieve its intended use and Indications for Use. The specific testing includes:

- Sterilization validation in accordance with ISO 11135:2014/Amd1:2018
- Biocompatibility evaluation in accordance with ISO 10993-1:2018 and the FDA Guidance Document, *"Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process',"* issued September 8, 2023.
- Comprehensive software verification and validation
- Electrical, mechanical, and thermal (EMT) safety and electromagnetic compatibility (EMC) testing in accordance with IEC 60601-1:2020, IEC 60601-1-6:2020, IEC 60601-2-37:2015, and IEC 60601-1-2:2014
- Comprehensive benchtop design verification and validation testing of the Catheter in accordance with ISO 10555-1:2013 and the recommendations of the FDA Guidance entitled, *"Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters – Premarket Notification (510(k)) Submissions,"* issued April 14, 2023.
- Comprehensive benchtop design verification testing of the SLT IVUS System in compliance with FDA Guidance Document entitled, *"Marketing Clearance of Diagnostic Ultrasound Systems and Transducers,"* issued February 21, 2023, including acoustic safety testing in accordance with Track 1 recommendations.
- Measurement accuracy evaluation of the proposed device in agar phantoms, including comparative testing against the primary predicate device.
- A human cadaver study evaluating the measurement performance of the proposed device relative to the primary predicate device in peripheral vessels.
- A GLP animal study comparing the proposed device relative to the primary predicate device with respect to vascular damage and tissue reaction.
- A summative Human Factors usability validation study, performed as a part of the usability engineering process, evaluating the use of the SLT IVUS System by its intended users in a simulated use environment.

These tests confirmed that any technological differences between the proposed device and the selected predicate devices do not raise different questions of safety or effectiveness. The results of

the tests support that the proposed device is at least as safe and as effective as the predicate devices for the same intended use.

Clinical Testing Summary

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

Overall Testing Summary & Conclusion

The tests demonstrated that the proposed device functions as intended for its proposed intended use and Indications for Use. These results further support that the proposed device performs at least as well as the predicate devices for the same intended use and confirm that any differences in technological characteristics do not raise different questions of safety or effectiveness.