October 22, 2025

Yorlabs, Inc.
Wanda Carpinella
Regulatory Consultant
2210 Faraday Avenue, Suite 100
Carlsbad, California 92008

Re: K250955
Trade/Device Name: XC11 ICE System, USA
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, IYN, IYO, ITX
Dated: September 22, 2025
Received: September 22, 2025

Dear Wanda Carpinella:

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,

Hetal B. Odobasic -S

for

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250955

Please provide the device trade name(s).

XC11 ICE System, USA

Please provide your Indications for Use below.

The XC11 ICE Box Ultrasound System is intended for intra-cardiac and intra-luminal ultrasound imaging when operated with the XC11 ICE Catheter and XC11 ICE System Handle.

The XC11 ICE Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

The XC11 ICE Catheter is for use with YorLabs XC11 ICE System Handle only.

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Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Summary
Traditional Premarket Notification 510(k) Summary
YorLabs XC11 ICE System, USA
510(k) Number K250955

Date Prepared: October 21, 2025

I. SUBMITTER

YorLabs, Inc.
2210 Faraday Avenue, Suite 100
Carlsbad, CA 92008

Contact Person
Glen McLaughlin, PhD
YorLabs, Inc.
2210 Faraday Avenue, Suite 100
Carlsbad, CA 92008

II. DEVICE

Name of Device: XC11 ICE System, USA
Common or Usual Name: Intracardiac imaging system
Classification Regulation: 21 CFR § 897.1200
Regulation Name: Diagnostic Intravascular Catheter
Product Codes: OBJ (Class 2) – Catheter, Ultrasound, Intravascular
IYN, IYO, ITX

III. PREDICATE

Primary Predicate: Acuson P500 Ultrasound Imaging System (K163396)
Secondary Predicate: AcuNav Diagnostic Ultrasound Catheter 8F, 10F (K071234)

IV. DEVICE DESCRIPTION

The XC11 ICE System, USA is a fully integrated imaging platform designed for wireless communications and a compact footprint. It provides precise, real-time visualization of intracardiac anatomy and devices positioned within the heart.

The System is comprised of two main components:

XC11 ICE Catheter (2D), USA

A 9F, single-use, sterile device capable of real-time 2D side-view imaging for intracardiac and intraluminal ultrasound in adult and pediatric patients. The catheter features easy steering maneuverability via deflection and rotation, along with on-handle imaging controls for enhanced usability.

XC11 ICE Box Ultrasound System, USA

This unit houses the image data acquisition and computer modules for image display and includes a connector for interfacing with the XC11 ICE System Handle. The XC11 ICE Tablet with a touchscreen interface, enables technicians to control the system software efficiently.

V. INDICATIONS FOR USE

The XC11 ICE Box Ultrasound System is intended for intra-cardiac and intra-luminal ultrasound imaging when operated with the XC11 ICE Catheter and XC11 ICE System Handle.

The XC11 ICE Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

The XC11 ICE Catheter is for use with YorLabs XC11 ICE System Handle only.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISICS WITH PREDICATES

Intended Use

The subject device and predicate are ultrasound system intended for intracardiac echocardiography (ICE) using a catheter-based ultrasound probe. The XC11 ICE System is designed primarily for interventional cardiology procedures that utilize catheter-based ICE imaging. It is not intended for diagnostic ultrasound imaging. As such, reference to diagnostic ultrasound procedures have been removed from the indications for use for the subject device.

Technological Features

The XC11 ICE Box Ultrasound System shares similar technological features to the ACUSON P500 Ultrasound System, and the XC11 ICE Catheter is technologically consistent to the AcuNav Ultrasound Catheter 8F and 10F used for intracardiac echocardiography.

The design of the XC11 ICE Box Ultrasound System is simplified compared to the ACUSON P500 Ultrasound System with only the features necessary for interventional catheterization procedures that use ICE imaging for guidance only. The XC11 ICE Box Ultrasound System, like the ACUSON P500 Ultrasound System, support wireless-enabled connectivity to its components.

The XC11 ICE Catheter, like the AcuNav Ultrasound Catheter 8F and 10F, incorporates a 64-element phased array transducer embedded at catheter's distal tip for 2D imaging, and it has steering mechanism controls through four-way articulation to manipulate the imaging orientation to facilitate intracardiac imaging.

VII. Summary of Non-Clinical Tests

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The XC11 ICE System complies with FDA-recognized standards:

- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/A2:2021
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbance - Requirements and Tests, Edition 4.1, 2020
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, Edition 2.1, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within Risk Management Process, Fifth edition, 2018
- ISO 14971, Application of risk management to medical devices, 2019

- IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related medical diagnostic ultrasonic fields, Edition 2.1, 2017
- ANSI C63.27 /D1.0: American National Standards Institute - Standard for Evaluation of Wireless

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification &Validation)
- GLP Animal Study

VIII. Summary of Clinical Tests

The subject of this premarket submission, XC11 ICE System, did not require clinical studies to support substantial equivalence.

IX. CONCLUSION

In conclusion, the XC11 ICE System is as safe and effective as the commercially available predicate for its intended use as demonstrated by the performance data for the subject device and is deemed substantially equivalent.