



July 11, 2025

ACCUTOME, INC. Doing Business As Keeler USA
% Sonia Bargotta
Senior Regulatory Affairs Associate
Keeler Ltd
Clewer Hill Road
Windsor, Berkshire SL4 4AA
United Kingdom

Re: K243227

Trade/Device Name: B-Scan
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 10, 2025
Received: June 10, 2025

Dear Sonia Bargotta:

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
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Enclosure

Indications for Use

Submission Number (if known)

K243227

Device Name

B-Scan

Indications for Use (Describe)

The B-Scan module is used for imaging the internal structure of the eye, including the opaque media and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye. The probe is intended to be used on both adult and pediatric patients that require imaging of the eye.

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

K243227

I. SUBMITTER

ACCUTOME, INC. Doing Business As Keeler USA
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Date Prepared: 18 March 2025

II. Device

Trade Name of the Device: B-Scan
Model Number: B-Scan - Connect
B-Scan - 4Sight
Common Name: Ultrasound B-Scan
Classification: System, Imaging, Pulsed Echo, Ultrasonic
Regulation Number: 21 CFR 892.1560 (Ultrasound pulsed echo imaging system)
21 CFR 892.1570 (Diagnostic ultrasonic transducer)
Regulatory Class: Class II
Review Panel: Radiology
Product Code: IYO (21 CFR 892.1560)
ITX (21 CFR 892.1570)

III. Predicate Device

B-Scan Plus, Manufactured by Accutome, Inc. (DBA Keeler USA) – K070943

IV. Reference Device

No reference devices were used in this submission

V. Indications for Use

The B-Scan module is used for imaging the internal structure of the eye, including the opaque media and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye. The probe is intended to be used on both adult and pediatric patients that require imaging of the eye.

VI. Device Description

The B-Scan device is designed as an ultrasound B-Scan, which uses pulsed echo ultrasound to image the structure of the eye. It utilizes an eye-contact probe to generate and receive the ultrasound pulse signals and provides a graphic display of returning pulse echoes to indicate the various structures.

All of the critical functions of the B-Scan are calculated in the same manner as in the predicate device, B-Scan Plus. The software algorithms for clinically critical functions remain the same as in the predicate device. However, the user interface and the workflow of B-Scan have enhancement to support cybersecurity implementation.

Both the subject device and predicate device are compatible with the Connect Software (K070943, K123349) and 4Sight (K152573). The software improvements in Connect were focused on enhancing features that optimize integration with the personal computer's processing, data storage, display, and printing capabilities.

The energy source for the B-Scan is USB power as in the predicate device, B-Scan Plus.

The software utilized on both the Connect and 4Sight platforms is fundamentally identical in core clinical functions, including image scanning, rendering, IOL calculations, data storage, and report formatting. Additionally, the key features within the B-Scan module do not differ significantly between the two systems, nor do they make an impact on the established clinical workflow.

Track 1 is being followed for this 510(k) submission.

VII. Comparison of Technological Characteristics with the Predicate Device

Table 1: General Comparison with Predicate Device

Item	Subject Device (B-Scan)	Predicate Device (K070943)	Remarks
Product Code	IYO ITX	IYO ITX	Same
Regulation No.	21 CFR 892.1560 (Ultrasound pulsed echo imaging system) 21 CFR 892.1570 (Diagnostic ultrasonic transducer)	21 CFR 892.1560 (Ultrasound pulsed echo imaging system) 21 CFR 892.1570 (Diagnostic ultrasonic transducer)	Same
Class	Class II	Class II	Same
Indications for use	The B-Scan module is used for imaging the internal structure of the eye, including the opaque media and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye. The probe is intended to be used on both adult and pediatric patients that require imaging of the eye.	The instrument is used for imaging the internal structure of the eye, including the opaque media and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye.	Same
Single Use	No	No	Same
Prescription Use / Over-the Counter Use	Prescription Use	Prescription Use	Same

Table 2: Comparison of Technological Characteristics with Predicate Device

Item	Subject Device (B-Scan)	Predicate Device (K070943)	Remark
Length	18.72 cm	17.78 cm	SE
Diameter	3.11 cm	3.18 cm	SE
Weight	141 g	101g	SE
Profile of membrane	Hyperbolic Paraboloid	Flat profile	SE
Environmental conditions			
Operating environmental conditions	Temperature: 10°–35°C (50°–95°F) Relative Humidity: 20-80% (non-condensing) Atmospheric Pressure: 800-1060 hPa	Temperature: 10°–40°C (50°–104°F) Relative Humidity: 20-80% (non-condensing) Atmospheric Pressure: 700-1060 hPa	SE
Storage and transport environmental conditions	Temperature: -40°–70°C (-40°–158°F) Relative Humidity: 15-90% (non-condensing) Atmospheric Pressure: 700-1060 hPa	Temperature: -20°–60°C (-4°–140°F) Relative Humidity: 15-90% (non-condensing) Atmospheric Pressure: 500-1060 hPa	SE
Specifications and properties			
Frequency	12 MHz nominal	12 or 15 MHz	SE
Axial resolution	<=0.02mm	0.015 mm Electronic	SE
Lateral resolution	0.5mm	0.085 mm Electronic	SE
Gain	0-112 dB	0-110 dB	SE
Adjustable gamma	Default, Linear, S-Curve	Linear, S-Curve, Log, Color	SE
Scanning angle	60°	60°	Same
Field of view	67mm	12 MHz = 64 mm or 15 MHz = 52 mm	SE
Frame rate per second	15, 20	15, 30 max	SE
Sampling rate	4096 (points per line)	2048 (points per line)	SE
Scan lines per frame	256	256	Same
Focal point	24mm	22 mm	SE
Time Gain Compensation (TGC)	Yes	Yes	Same

Item	Subject Device (B-Scan)	Predicate Device (K070943)	Remark
Frozen image gain adjustment	Yes	Yes	Same
Zoom	2x optical zoom, 8x max	2x optical zoom, 8x max	Same
Reports	Pdf	Pdf	Same
Snapshot format	jpeg, bmp, png, tiff, gif	jpeg, bmp, png, tiff, gif	Same
Data archive / export capability	Yes	Yes	Same
Maximum number of frames per scan	240	256	SE
Size of cine loop	30-240 MB	16-128 MB	SE
Measurement calipers with velocity adjustment	4 line, 2 area, 2 angle	4 line, 2 area, 2 angle	Same
Depth of penetration	60 mm	<54 mm	SE
Frame buffer size	240	256	SE
Nominal gain range in hardware	60 dB	<50 dB	SE
Nominal focal length	23 mm	22 mm	SE
Host interface connector	USB 2 and 3	USB 2	SE
Power source	PC USB connection	PC USB connection	Same
Image preview	Same, image preview is displayed within 2 seconds of pressing probe button (average time recorded across 5 probes).	Same, image preview is displayed within 2 seconds of pressing probe button (average time recorded across 5 probes).	Same
Minimum PC specification	Windows 10 64bit OS CPU AMD or Intel Core i5 5th Generation minimum Screen resolution 1280 x 800 4 GB RAM 256 GB HDD recommended	Windows 7 64bit OS CPU AMD or Intel Core i3 5th Generation minimum Screen resolution 1280 x 1024 4 GB RAM 256 GB HDD recommended	SE
Compatibility with standalone Connect Software and 4Sight	Connect Software, version - Connect Version 9.00.31 (Major software version	Current (released version): 4Sight 2.08.00 Connect 8.03.01	SE

Item	Subject Device (B-Scan)	Predicate Device (K070943)	Remark
	release will be 9.01.00 during official release) 4Sight, version - 4Sight Version 3.00.31 (Major software version release will be 3.01.00 during official release)		
Transducer calibration data	Transducer calibration information is stored in the EEPROM located at the scan head. On power-up, the main board reads this data. The main board can be changed without losing transducer calibration data.	Transducer calibration information is stored in the EEPROM located on the main board.	SE
Warranty	3 years	3 years	Same
Biological characteristics			
Uses the same materials or substances in contact with the same human tissues or body fluids	Membrane tip: TPX MX004 (Polymethylpentene)	Membrane tip: TPX (Polymethylpentene)	SE
Similar kind and duration of contact with the same human tissues or body fluids	The tip of the probe contacts the eye of the patient or contacts the eyelid of the patient. Contact is for a very short duration, and even with repeated use the total duration of contact will be much less than 24 hours	The tip of the probe contacts the eye of the patient or contacts the eyelid of the patient. Contact is for a very short duration, and even with repeated use the total duration of contact will be much less than 24 hours	Same
Clinical characteristics			
Same clinical condition or purpose, including	Used for imaging the internal structure of the eye, including	Used for imaging the internal structure of the eye, including	Same

Item	Subject Device (B-Scan)	Predicate Device (K070943)	Remark
similar severity and stage of disease	the opaque media, anterior, and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye.	the opaque media, anterior, and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye.	
Same site in the body	Probe is used on the eye/eyelid	Probe is used on the eye/eyelid	Same
Similar population, including as regards age, anatomy and physiology	Probe is intended to be used on both adult and pediatric patients that are requiring internal imaging of the eye.	Probe is intended to be used on both adult and pediatric patients that are requiring internal measurements of the eye.	SE
Same kind of user	The probe is intended to be used by any trained professional in an ophthalmic clinic, including ophthalmic assistants, ophthalmic photographers, technicians, optometrists or ophthalmologists.	The probe is intended to be used by any trained professional in an ophthalmic clinic, including ophthalmic assistants, ophthalmic photographers, technicians, optometrists or ophthalmologists.	Same
Scanning Mode	B-Scan only	B-Scan only	Same
B-Scan Controls	Fixed depth (60mm), variable gain (0-112 dB), fixed frequency (12MHz)	Depth, gain, frequency, power, contrast and brightness	SE
B-Scan Depth	60 mm	30/50/60/100 mm	SE
Performance	12MHz: <u>60mm Depth Setting</u> <u>Line:</u> Clinical Accuracy: ±3% Accuracy Range: 60 mm <u>Area:</u> Clinical Accuracy: ±15% Accuracy Range: 60 mm	12MHz: <u>30mm Depth Setting</u> Distance Range: 30mm Distance Accuracy: 7.5% Area Range: 30mm Area Accuracy: 40% <u>60mm Depth Setting</u> Distance Range: 60mm Distance Accuracy: 3% Area Range: 60mm Area Accuracy: 22%	SE

Item	Subject Device (B-Scan)	Predicate Device (K070943)	Remark
		15MHz: <u>50mm Depth Setting</u> Distance Range: 50mm Distance Accuracy: 3% Area Range: 50mm Area Accuracy: 20% <u>100mm Depth Setting</u> Distance Range: 50mm Distance Accuracy: 7% Area Range: 50mm Area Accuracy: 14%	

Table 3: Applied Standards

Parameters	Subject Device (B-Scan)	Predicate Device (K070943)	Remark
Electrical Safety and EMC standards met	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37	SE
Sterility	Provided non-sterile	Provided non-sterile	Same
Biocompatibility	- Cytotoxicity - Ocular Irritation - Skin Sensitization	Material used in probe window is TPX (PolyMethyl Pentane)	SE

VIII. Performance Data

The subject device has been evaluated through a series of performance tests to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. All the tests conducted on the device are summarized below:

Cleaning and disinfection

Procedures related to the disinfection and cleaning have been detailed in the Instruction for Use. The reprocessing validation test was conducted on the proposed device.

Biocompatibility testing

The proposed device has been tested and met the requirements according to the ISO 10993 series standard for Biocompatibility.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance, "Content of Premarket Submissions for Device Software Functions".

Cybersecurity compliance was implemented, and documentation was provided in accordance with FDA's guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Thermal, mechanical, and electrical safety and electromagnetic compatibility

The proposed device has been tested and met the requirements according with the safety standard IEC 60601-1, IEC 60601-1-2.

Bench Test

The bench tests conducted on the proposed device are listed below.

- Accelerated Thermal Cycling Test
- Plastic Component UV Assessment
- Transit Performance Test
- USB cable Pull Test
- Physical Accuracy and Range Test
- Button actuator Validation Test
- Repeated Reprocessing Validation Test
- B-Scan Integrated Life Testing Verification Report

IX. Substantial Equivalence Conclusion

The indications for use, intended use environment, and intended user profile of the new subject device, the B-Scan, are the same as those of the predicate device. The user interface of the new model has been enhanced to support cybersecurity and offers improved user interaction for enhanced usability. The technological characteristics, including the device design and system architecture, particularly how it interacts with different mechanical and electrical components, differ from the predicate device, B-Scan Plus. However, these differences do not raise any new questions regarding safety or effectiveness. The biological characteristics, clinical characteristics, and the application of the subject device are also the same as those of the predicate. The subject device operates in the same use setting and under the same environmental conditions. All performance testing met or exceeded the acceptance criteria, confirming that the subject device functions within its design specifications and demonstrates equivalent or superior performance to the predicate device. The conclusions drawn from the performance testing demonstrate that the subject device, the B-Scan is as safe and is substantially equivalent to the legally marketed device, B-Scan Plus (K070943).