



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Analogic Corporation
% Mr. Michael Doyle
Global Director Regulatory & Clinical Affairs
8 Centennial Drive
PEABODY MA 01960

June 15, 2016

Re: K161342
Trade/Device Name: Sonic Window
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX, IYN
Dated: May 17, 2016
Received: May 18, 2016

Dear Mr. Doyle:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive, slightly slanted style.

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

Enclosure

Indications for Use

510(k) Number (if known)

K161342

Device Name

Sonic Window

Indications for Use (Describe)

The Sonic Window is intended for the visualization of vessels and vascular access guidance of needles and catheters (Insertion of Peripheral Intra Venous (PIV) Catheters, as an example). The Sonic Window is not indicated for use by a layperson and shall be used by prescription only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Ultrasound Indications for Use Table

Fill out one form for each ultrasound system and each transducer.

System: Sonic Window (SW1000)

Intended Use: Diagnostic ultrasound imaging and visualization of vessels for vascular access guidance of needles and catheters as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Peripheral vascular							N*

*= Coronal plane (Constant Imaging Depth Plane)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)



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8. 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR 807.92

A. Submitter's information

Name: Analogic Corporation
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Peabody, MA 01960
United States
FDA Establishment Owner / 1220672
Operator Number:
Contact person: Michael J. Doyle
Phone: 978-326-4410
Fax: 978-977-6809
Manufacturer: Analogic Corporation
8 Centennial Drive
Peabody, MA 01960
United States

B. Device Name:

Trade/Proprietary Name: Sonic Window
Common Name: Ultrasound system
Classification name: Ultrasonic Pulsed Echo Imaging System
Regulation Medical Specialty: Radiology
Review Panel: Radiology
Product Code: IYO, ITX, IYN
Regulation Number: 892.1560, 892.1570, and 892.1550
Device Classification: 2
Submission type: Special 510(k)
Model: SW1000

C. Substantial Equivalence:

This submission is a Special 510(k) Device Modification as described in the FDA's Guidance document entitled, "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". In support of this Special 510(k), Analogic Corporation has provided certification of compliance to 21 CFR §820.30 Design Control requirements. Design validation testing was performed to ensure that the Sonic Window with modifications meets design specifications. The Sonic Window with modifications has been compared to the legally marketed predicate device as cleared through K140126 (March 4, 2014) and was found to be substantially equivalent.



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D. Device Description/Indications for Use:

The Sonic Window with the addition of software to perform and display ultrasound fluid flow analysis is a fully integrated handheld ultrasound imaging system that displays real-time ultrasound images on a coronal plane at a constant depth from the transducer. The depth is controllable by the operator. The Sonic Window system consists of the Sonic Window handheld device, the Docking Station/Charger and the AC Adapter. The Sonic Window uses an imaging mode, C-Mode, which provides the visualization in the coronal plane of peripheral vessels and assessment of vessels width and depth for needle/catheter placement.

Indications for Use:

The Sonic Window is intended for the visualization of vessels and vascular access guidance of needles and catheters (Insertion of Peripheral Intra Venous (PIV) Catheters, as an example). The Sonic Window is not indicated for use by a layperson and shall be used by prescription only.

E. Technological Characteristics

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the currently marketed predicate device.

F. Summary of Non-clinical Test/Performance Testing - Bench:

Analogic Corporation believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indication for use. Performance, verification and validation testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria was met. Results of this testing have confirmed that the proposed device is substantially equivalent to the predicate device and is suitable for the labeled indication for use.

Acoustic output:

The Sonic Window transducer system controlling the acoustic output is equivalent to the predicate device. The system will assure that the acoustic output will always stay below the pre-amendment upper limits i.e. $I_{spta} \leq 720 \text{ mW/cm}^2$ and $MI < 1.9$.

The Acoustic Output reporting is made according to the standards required by the FDA Guidance: *“Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008)”*.