APR 0 4 2014

K140126
Page 1 of 5

analogic

Innovative Solutions for Life

510(k) Summary
For
Analogic Corporation

Sonic Window

1. Date this Summary was Prepared:

January 30, 2014

2. Submitter's Name and Address:

Submitter's Name:	Analogic Corporation
Address:	8 Centennial Drive
City, State, and Zip:	Peabody, Massachusetts 01960
Registration Number:	1220672

3. Contact Person:

Name:	Albert C. Cefalo
Title:	Senior Manager Global Regulatory Affairs
Telephone:	(978) 326-4000
Facsimile:	(978) 977-6803
E-mail:	ccefalo@analogic.com

4. Device Name:

Proprietary or Trade Name:	Sonic Window
Common Name:	Ultrasound System
Model Name:	**SW1000**
Classification Name:	Ultrasonic Pulsed Echo Imaging System
Classification Panel:	Ultrasonic Imaging Devices
Product Codes:	IYO, ITX
Code of Federal Regulations:	892.1560, 892.1570

Regulatory Classification of Sonic Window

Device Panel	CFR Section	Product Code	Device Class	Description
Part 892- Radiology Devices	892.1560	IYO	II	Ultrasonic Pulsed Echo Imaging System
Part 892- Radiology Devices	892.1570	ITX	II	Diagnostic Ultrasound Transducer

5. Predicate Devices:

The legally marketed devices to which equivalence is being claimed are:

The Flex Focus cleared under Premarket Notification K100919 (Summary is included in Appendix C along with the User Guide, the Transducer User Guide and Transducer Data Sheet). This predicate device was chosen specifically for its use on peripheral vascular viewing and its ability to perform in C-Mode with the assistance of additional software. Additionally the BK Model Flex Focus Ultrasound Transducer Probe 8848 (cleared under K081154) was chosen as this predicate probe uses the same patient contact materials.

6. Description of Sonic Window

The Sonic Window is a fully integrated handheld ultrasound imaging system that combines electronics, transducer, display and battery into the same device. The device is designed and optimized to visualize real-time ultrasound images on a Coronal (Constant Imaging Depth) plane positioned at a distance (depth) from the transducer that is controllable by the user.

7. Intended Use:

Visualization of peripheral vessels and assessment of vessel width and depth for needle/catheter placement by a medical professional. The Sonic Window is only intended to be used by a health care professional by prescription only.

8. Comparison of Technological Characteristics:

The technological characteristics of the Sonic Window are the same as the legally marketed predicate devices.

The Sonic Window Acoustic Output controls are similar to the Output controls of the predicate device. The system will assure that the acoustic output always will stay *well below* the pre-amendment upper limits ice $I_{spta} \leq 720 mW/cm^2$ and MI ≤ 1.9 (Track 3, non-ophthalmic.

The Track 3 summary table as required by the FDA guidance *document Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; issued September 9, 2008* is provided below.

Transducer Model	Ispta.3	TI Type	TI Value	MI	$I_{PA.3}$ at MI_{max}
Sonic Window	$3.4 mW/CM^2$	TIS	0.16	0.29	$7.3 W/cm^2$

Summary of Technological Characteristics – Predicate Device Compared to Modified Device

Manufacturer / Features	Analogic	BK Medical
	Sonic Window	**Flex Focus**
	New Device	K100919 **w/ 8820E**
	Indications	**K081154 for Contact Materials (Probe 8848)**
Primary Market	Peripheral Vascular	Surgery, Anesthesia & Interventional Radiology including Peripheral Vascular
Type Of System	Handheld	Portable
Operating Modes	C-Mode [1]	B, M, Doppler, CFM, PW, THI, ***3D***[2]
Source Of Power	Battery	Line and Battery
Transducers	Integrated 5MHz 2D Array	Multiple multi-frequency probes
Contact Materials	TPX MX 002, Polymics Carbon Black	TPX MX 002, Polymics Carbon Black
Transducer Housing	Radel R-5100	TBD

[1] C (Coronal)-Mode. (Constant Distant Imaging Plane) in real-time
[2] 3D includes the functionality to visualize Coronal planes
[3] Indicates output of Peripheral Vascular Access Probe Model 4C-RS

9. Non-clinical Tests to be used in Determination of Substantial Equivalence:

Prior to marketing the Sonic Window, verification testing activities will be conducted to establish the compliance, performance, and reliability characteristics of the Sonic Window. This is to include the following non-clinical tests:

IEC 60601-1 (including Amendments 1 & 2), Medical Electrical Equipment - General Requirements for Safety

IEC 60601-1-2: 2001 Medical electrical equipment - Electromagnetic compatibility emission limits meet Group 1 Class B

IEC 60601-1-4: Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems

Mechanical shock and vibration tests will be performed in accordance with IEC 60068 series of standards to ensure the device withstands shocks and vibrations in environment of intended use.

Shipping container transportation tests will be performed in accordance with ISTA; Project 2A to ensure packaging of equipment is not adversely affected during shipping.

Altitude tests will be performed to ensure that operation at higher altitudes does not adversely affect electrical safety or performance.

Tests will be performed to verify enclosure material robustness and resistance to cleaning materials commonly used in hospitals.

10. Conclusions from Non-clinical Testing:

The test schedule of the Sonic Window combined with "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; issued September 9, 2008," Track 3 tests already performed demonstrate that the performance of the Sonic Window ultrasound system is substantially equivalent to the predicate devices cited in Paragraph 5 of this summary. The device will present no new concerns regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 4, 2014

Analogic Corporation
% Mr. Albert Cefalo
Senior Manager, Global Regulatory Affairs
8 Centennial Drive
PEABODY MA 01960

Re: K140126
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
Dated: January 31, 2014
Received: February 3, 2014

Dear Mr. Cefalo:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140126

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 Intravenous (PIV) Catheters as an example). The Sonic Window is not indicated for use by a layperson and shall be used by prescription only.

Sonic Window / SW1000

Mode of Operation

Clinical Application Other* (Specify)

Peripheral Vascular N*

* = Coronal Plane (Constant Imaging Depth Plane)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."