Quantel Medical
% Ms. Maureen O'connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
STONEHAM MA 02180

March 20, 2019

Re: K183414
Trade/Device Name: ABSOLU®
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO
Dated: February 27, 2019
Received: February 28, 2019

Dear Ms. O'connell:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183414

Device Name
ABSOLU®

Indications for Use *(Describe)*
The Quantel Medical ABSOLU is intended to be used for:
-Axial Length measurement of the eye by ultrasonic means;
-Implanted IOL power calculation, using the Axial Length measurement;
-Visualization of the interior of the eye and the orbit by A and B scans.

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.

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."

System: Absolu

Intended Use : Diagnostic ultrasound imaging of the human body as follows :

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic	P						(A-mode) P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-Skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication ; P=previously cleared by FDA ; E=added under Appendix E

*Examples of other modes of operation may include : A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and color Velocity Imaging

System: Absolu

Transducer : 15 MHz B-scan Probe (ref model number B1)

Intended Use : Diagnostic ultrasound imaging of the human body as follows :

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-Skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication ; P=previously cleared by FDA ; E=added under Appendix E

*Examples of other modes of operation may include : A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and color Velocity Imaging

System: Absolu

Transducer : 11 MHz Biometry Probe (ref model number : TP-01-b/ TP-02-las)

Intended Use : Diagnostic ultrasound imaging of the human body as follows :

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic							(A-mode) P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-Skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication ; P=previously cleared by FDA ; E=added under Appendix E

*Examples of other modes of operation may include : A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and color Velocity Imaging

System: Absolu

Transducer : Standardized A Probe (ref model number : STD-A : (8 MHz)

Intended Use : Diagnostic ultrasound imaging of the human body as follows :

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic							(A-mode) P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-Skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication ; P=previously cleared by FDA ; E=added under Appendix E

*Examples of other modes of operation may include : A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and color Velocity Imaging

System: Absolu

Transducer : 50 MHz Linear Probe (ref model number : Lin 50 : (50 MHz)

Intended Use : Diagnostic ultrasound imaging of the human body as follows :

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-Skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication ; P=previously cleared by FDA ; E=added under Appendix E

*Examples of other modes of operation may include : A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and color Velocity Imaging

System: Absolu

Transducer : B 20MHz -5A B-SCAN PROBE (ref model number : B20-5A: (20 MHz)

Intended Use : Diagnostic ultrasound imaging of the human body as follows :

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify) B/M	Other* (Specify)
Ophthalmic	Ophthalmic	E						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-Skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication ; P=previously cleared by FDA ; E=added under Appendix E

*Examples of other modes of operation may include : A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and color Velocity Imaging

510(k) SUMMARY

Quantel Medical
ABSOLU® K183414

510(k) Owner

Quantel Medical
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Contact Person: Bruno Pagès

Submission Correspondent:

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O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: February 26, 2019

Trade Name of Device

ABSOLU ®

Common or Usual Name

Ultrasonic Pulsed Echo Imaging system

Classification Name

Ultrasonic Pulsed Echo Imaging system; 21 C.F.R. 892.1560
Class II
Product Code: IYO

Predicate Device

Quantel Medical AVISO (K051851)

Device Description

The ABSOLU is a high definition multifunction ophthalmic ultrasound system used for the following intended use:

- Axial Length measurement of the eye by ultrasonic means;
- Implanted IOL power calculation, using the axial length measurements;
- Visualization of the interior of the eye and the orbit by A and B scans.

The following probes are compatible with Absolu depending upon the different configurations with the panel of probes chosen:

Probe	ABSolu B	ABSolu S	ABSolu B with a B 20 annular option	ABSolu S with a B 20 annular option
Biometry A-probe	Yes	Yes	Yes	Yes
Biometry A-probe with a laser aiming beam	Yes	Yes	Yes	Yes
Standardized A-probe	No	Yes	No	Yes
B15MHz probe	Yes	Yes	Yes	Yes
Linear 50MHz probe	Yes	Yes	Yes	Yes
B20MHz annular probe	No	No	Yes	Yes

Intended Use / Indications for Use

The Quantel Medical ABSOLU is intended to be used for:

- Axial Length measurement of the eye by ultrasonic means;
- Implanted IOL power calculation, using the Axial Length measurement;
- Visualization of the interior of the eye and the orbit by A and B scans.

Substantial Equivalence

Quantel Medical believes that the ABSOLU ® described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device, the Quantel Medical AVISO cleared in K051851.Yes, the predicate device for ABSOLU® is AVISO cleared in K051851.

2. Do the devices have the same intended use?

Yes, the indications for use statement for the ABSOLU® is exactly the same as the indications for use statement for the predicate device. Additionally, both of the devices are prescription devices which are intended to be used by trained medical personnel. The use of the different parameters of the ABSOLU® and the predicate device are under control of the physician for the different phases of the diagnostic. Therefore, the ABSOLU® has the same intended use as the identified predicate device and may be found to be substantially equivalent to the predicate device.

3. Does the new device have the same technological characteristics?

The ABSOLU ® has minor technological differences compared to the predicate device, which is a previous version of the same device. The technical differences are the following:

- Physical Characteristics: revised dimensions and cosmetics. Re-design of the device to be more compact.

- User Interface is more intuitive, divided into 4 sub-sections (general set-up, patient's management, exams and edition report (s)).
- A modification of the B-scan probe (20 MHz) technology. The new annular technology offers the opportunity to increase the depth of field by 70%. This improvement permits simultaneous examination of pathologies of the vitreous, the retina and the orbit without compromising on image quality.
- A modification of the B-scan probe (15 MHz) technology. The transducer frequency of the B-scan probe has been increased from 10 MHz for the cleared Aviso to 15 MHz for the new version. This variation of frequency does not affect the safety or performance of the device. The new 15 MHz probe has a superior resolution and thus may allow more favorable diagnostics. The focal point has changed from 25 mm to 24 mm, which is not considered significant because the target is to focus in the retina (which is about 24 mm). The measurement accuracy has also been improved, due to the increase of the frequency.
- The Lin 25 probe has been removed in the ABSOLU. This probe is no longer required.
- General Software: the software has been revised to accommodate the other device changes listed here.

Performance data is available to support the technological changes. The changes to the physical characteristics were supported by electrical safety and electromagnetic compatibility testing. The changes to the user interface were shown to be in compliance with IEC 60601-1-6. The changes to the B-scan probes are in compliance with IEC 60601-2-37. Ultrasound testing was performed using Track 1.

Therefore, in summary, the new device has the same indications for use and similar technological characteristics to the predicate device and is therefore, substantially equivalent. Performance data support substantial equivalence of the different technological characteristics.

Performance Data

Performance testing was conducted in order to demonstrate compliance with recognized consensus standards:

- AAMI ANSI ES60601-1:2005 + Corr. 1:2006+Corr. 2:2007+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014: Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
- IEC 60601-1-6:2010+A1:2013 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard Usability

- IEC 60601-2-37: "Ed2 + AM1 with 60601-1 (ed.3), AM1 with correc 1 & correc 2 Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

Additionally, hardware and software validation activities were performed to ensure the device performed as intended and software documentation appropriate for the Moderate level of concern was provided.