Quantel Medical
℅ Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

March 2, 2018

Re: K180265
Trade/Device Name: COMPACT TOUCH® Ophthalmic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: February 26, 2018
Received: February 27, 2018

Dear Mr. Job:

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.

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.

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

Robert Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180265

Device Name
COMPACT TOUCH® Ophthalmic Ultrasound System

Indications for Use *(Describe)*

The COMPACT TOUCH Ophthalmic Ultrasound System and the probes that are used with it are indicated for diagnostic imaging and biometric measurement of the eye including:

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

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.

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System: Compact Touch

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

P=Previously cleared in K094038

System: Compact Touch

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	N						
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

System: Compact Touch

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

P=Previously cleared in K094038

System: Compact Touch

Transducer : Pachymetry Probe (ref model number : P1 : (20 MHz A-scan)

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

P=Previously cleared in K094038

510(k) SUMMARY

Quantel Medical
COMPACT TOUCH® Ophthalmic Ultrasound System

510(k) Owner

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Date Prepared: February 28, 2018

Trade Name of Device

COMPACT TOUCH OPHTHALMIC ULTRASOUND SYSTEM

Common or Usual Names

Ultrasonic Pulsed Echo Imaging system

Ultrasonic Diagnostic Transducer

Classification Names

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

Transducer, Ultrasonic, Diagnostic; 21 C.F.R. 892.1570
Class II
Product Codes: ITX

Predicate Device

Quantel Medical Compact Touch (K094038)

Device Description

The COMPACT TOUCH Ophthalmic Ultrasound System is an ultrasonic system for ophthalmology. It is a modification to the COMPACT TOUCH® cleared in K094038. Similar to the previous version of the device, it consists of a base and probes. The Base performs the same calculations and displays as the predicate COMPACT TOUCH®. The A-scan probe for biometry and pachymeter is identical to the predicate while the B-scan probe has an increased transducer frequency of 15 Hz which allows for improved measurement accuracy of ± 0.115 mm.

Intended Use / Indications for Use

The COMPACT TOUCH Ophthalmic Ultrasound System and the probes that are used with it are indicated for diagnostic imaging and biometric measurement of the eye including:

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

Substantial Equivalence

The COMPACT TOUCH Ophthalmic Ultrasound System 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 which is the Quantel Medical COMPACT TOUCH® (K094038). The indications for use statement for the COMPACT TOUCH Ophthalmic Ultrasound System is exactly the same as the indications for use statement for the predicate device.

The COMPACT TOUCH Ophthalmic Ultrasound System and the predicate device, the previous version of the same device, are equivalent regarding technological characteristics. Both systems include diagnostic imaging with biometry and pachymetry performed with an A-Scan probe and diagnostic imaging and axial length measurements performed with a B-Scan probe. The A-scan probe used in both systems is identical with the same transducer used in both systems.

There have been minor modifications to the B-Scan probe where the transducer frequency of the B-scan probe has been increased from 10 MHz for the cleared COMPACT TOUCH® to 15 MHz for the new version. This variation of frequency does not affect the safety or performance of the device. The IEC 60601-2-37 tests have been followed in order to cover the new transducer specification (the MI value is inferior to 0.23).

All other aspects of the two systems remain identical with the exception of the following items which have been determined not to impact the safety and effectiveness:

- Physical Characteristics: revised dimensions and look of device and addition of Wi-Fi connection. Electrical safety and electromagnetic compatibility testing have been

performed which shows the new version of the device continues to comply with the electrical safety standards.

- Electronic: the degree of protection against electric shock has been changed from BF to B due to the change of the power supply. The IEC 60601-1 tests have been followed in order to cover this new configuration.
- Measurement accuracy has been improved (from ± 0.2 mm to ± 0.115 mm) due to the increase of the frequency of the probe.
- General Software: the software has been revised to accommodate the other device changes listed here.
- Documentation: an HDMI port has been added to the device.

In summary, the new version of the COMPACT TOUCH Ophthalmic Ultrasound System has the same indications for use and similar technological characteristics to the predicate device and is therefore, substantially equivalent.

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 60601-1-2:2007: 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 62366-1 Medical Devices-Part 1: Application of usability engineering to medical devices
- 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.