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

November 15, 2021

Re: K213254
Trade/Device Name: AXIALIS Ophthalmic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: September 29, 2021
Received: September 30, 2021

Dear Maureen 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/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 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213254

Device Name
AXIALIS Ophthalmic Ultrasound System

Indications for Use *(Describe)*
The AXIALIS Ophthalmic Ultrasound System and the probes that are used with it are indicated for diagnostic imaging and biometric measurement of the eye including:
• 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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510(k) SUMMARY
K213254

Quantel Medical
AXIALIS Ophthalmic Ultrasound System

510(k) Owner
Quantel Medical
11 rue Bois Joli
CS40015
63808 Cournon D'Auvergne-Cedex
France

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

Date Prepared: November 4, 2021

Trade Name of Device
AXIALIS Ophthalmic Ultrasound System

Common or Usual Name
Ultrasound pulsed echo imaging system
Ultrasound diagnostic transducer

Classification Name
System, Imaging, Pulse Echo, Ultrasound; 21 C.F.R. §892.1560
Class II
Product Code: IYO

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

Predicate Device(s)
Quantel Medical Compact Touch Ophthalmic Ultrasound System cleared in K180265

Device Description
The AXIALIS Ophthalmic Ultrasound System is an ultrasonic system for ophthalmology which consists of a base and probes. The base performs the same calculations and displays as the

predicate device, the Quantel Medical COMPACT TOUCH. The A-scan probe for biometry and pachymetry is identical to the predicate device.

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

- 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
Quantel Medical believes that the AXIALIS 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 cleared in K180265. The intended use of both devices is diagnostic imaging and biometric measurement of the eye.

The AXIALIS has the same technological characteristics as the predicate device with the exception that the AXIALIS does not include the functionality related to the B-probe and does not include B-scan diagnostic imaging software. All other specifications and features are substantially equivalent between the AXIALIS and the COMPACT TOUCH.
Therefore, the AXIALIS is substantially equivalent to the COMPACT TOUCH predicate device.

Performance Data
Non-clinical testing was performed to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device.

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 2010, AMD 1: 2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Usability
- IEC 60601-2-37 Edition 2.1 2015 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.