April 26, 2024

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

Re: K232302
Trade/Device Name: Pocket III
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO
Dated: March 27, 2024
Received: March 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
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OHT8: Office of 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)*
K232302

Device Name
Pocket III

Indications for Use *(Describe)*
The Pocket III is intended to be used in ophthalmology clinical applications for measurement of corneal thickness by ultrasonic means with pachymetry. This device should be operated by doctors or other appropriately-trained healthcare professionals and should be used in health institutions. The device is not intended for fetal use.

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.

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K232302

510(k) SUMMARY

Quantel Medical
Pocket III

510(k) Owner
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France

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

Date Prepared: April 19, 2024

Trade Name of Device
Pocket III

Common or Usual Name
Ultrasonic Imaging System

Classification Name
System, Imaging, Pulsed Echo, Ultrasonic

Product Codes:
IYO

Device Classification
Class II
21 C.F.R. §892.1560

Predicate Device(s)
Quantel Medical Pocket Ultrasonic Pachymeter cleared in K993674

Device Description
The Pocket III is a small hand-held device in pen-shaped design. Measurement results appear numerically on the LCD graphic display. The user can perform a basic cable transfer (USB-C) or activate Bluetooth to export data to a computer.

The Pocket III is equipped with an integrated 30 MHz pachymetry probe. The ultrasonic transducer makes contact with, and transmits ultrasonic pulses through, the surface cornea. Echoes are returned from the anterior and posterior surfaces of the cornea.

Indications for Use
The Pocket III is intended to be used in ophthalmology clinical applications for measurement of corneal thickness by ultrasonic means with pachymetry. This device should be operated by doctors or other appropriately-trained healthcare professionals and should be used in health institutions. The device is not intended for fetal use.

Substantial Equivalence
Quantel Medical believes that the Pocket III 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 following is a tabular presentation of the Pocket III compared with the predicate device which is the Quantel Medical Pocket Ultrasonic Pachymeter cleared in K993674.

Pocket III Substantial Equivalence

Manufacturer	**QUANTEL MEDICAL**	**QUANTEL MEDICAL**
Model	Pocket III	Pocket
510 (K) Number	-	K993674
Intended Use	Corneal thickness measurement	Corneal thickness measurement
Indications for Use	The Pocket III is intended to be used for the measurement of corneal thickness by ultrasonic means.	The Quantel Medical Pocket Ultrasonic Pachymeter is intended to be used for the measurement of corneal thickness by ultrasonic means, which is required for some types of corneal surgery.
Clearance Type	Prescription	Prescription
Technology	Ultrasound	Ultrasound
Application	Ophthalmic pachymeter	Ophthalmic pachymeter
Patient contacting material	Polystyrene (Rexolite 1422)	Polystyrene (Rexolite 1422)
Probe reference	P2	P1
Type	A	A
Transducer Frequency	30 MHz	20 MHz
Tip Diameter	1.2 mm	1.2 mm
Resolution	1 micron	1 micron
Accuracy	+/- 5 microns	+/- 5 microns
Focal point	0.5 mm from tip	0.5 to 2 mm from tip
Angle	35 degrees	45 degrees
Thermal Index	<1	<1
Corneal thickness range	150-1200 microns	200-1300 microns
IOP Formula	Ehlers	Ehlers

	Doughty Dresdner	Doughty Dresdner
Power	3.7 V Lithium Ion battery and external AC/DC wall mount adapter 5V 10W	Battery, external power supply
Electrical Safety	Per IEC 60601-1	Per IEC 60601-1
EMC	Per IEC 60601-1-2	Per IEC 60601-1-2
Biocompatibility	Per ISO 10993-1 for surface device, intact skin, limited duration	Per ISO 10993-1 for surface device, intact skin, limited duration
Ultrasound Safety	Per IEC 60601-2-37	Per IEC 60601-2-37

The intended use of the Pocket III is the same as the intended use of the predicate device and the indications for use are also nearly identical. Both devices are prescription devices for use by trained healthcare providers. The Pocket III has the same technological characteristics as the predicate device as described in the table above. Both devices are ophthalmic ultrasonic pachymeters for measurement of corneal thickness. The specifications for both devices are similar and both devices comply with IEC 60601-2-37. Both are powered by a power supply or a battery. Both devices meet electrical safety and EMC standards and both are made from the same biocompatible patient contacting materials. Both devices use the same three formulae for correction of a measurement in accordance with IOP. Therefore, the Pocket III is substantially equivalent to the 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.

- AAMI ANSI ES60601-1 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 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 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard Usability
- IEC 60601-2-37 Medical electrical equipment-Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62133-2 Edition 1.0 2017 Secondary cells and batteries containing alkaline or other non-acid electrolysis-Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications-Part 2: Lithium systems.

Pachymetry measurements recorded with test blocks were verified for all available freeze acquisition measuring modes (Easy, Medium and Hard) from 208 μm to 1042 μm of theoretical

value of test block. After measurements, all results are acceptable and compliant with an accuracy of ±5μm.

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

In conclusion, non-clinical testing supports substantial equivalence to the predicate device.