May 1, 2024

Reichert, Inc.
Elizabeth Schultz
Manager, Regulatory Affairs
3362 Walden Avenue, Suite 100
Depew, New York 14043

Re: K233516
Trade/Device Name: Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes (16305, 16306, 16318)
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: March 22, 2024
Received: March 25, 2024

Dear Elizabeth Schultz:

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,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233516

Device Name

Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes (16305, 16306, 16318)

Indications for Use *(Describe)*

The Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes is intended to be used for the measurement of intraocular pressure of the human eye.

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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510(k) #: K233516	510(k) Summary
Contact Details	**21 CFR 807.92(a)(1)**
Applicant Name	Reichert, Inc.
Applicant Address	3362 Walden Avenue Suite 100 Depew NY 14043 United States
Applicant Contact Telephone	716-686-4568
Applicant Contact	Ms. Elizabeth Schultz
Applicant Contact Email	Elizabeth.Schultz@ametek.com
Device Name	**21 CFR 807.92(a)(2)**
Device Trade Name	Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes (16305, 16306, 16318)
Common Name	Tonometer and accessories
Classification Name	Tonometer, Manual
Regulation Number	886.1930
Product Code	HKY

Legally Marketed Predicate Devices		**21 CFR 807.92(a)(3)**
Predicate #	**Predicate Trade Name (Primary Predicate is listed first)**	**Product Code**
K153694	Icare Ic100	HKY

Device Description Summary **21 CFR 807.92(a)(4)**

Device Description [807.92(a)(4)]

a. Physical Description:

The Reichert Tono-Vera® Tonometer is a hand-held, battery powered instrument that utilizes rebound methodology to measure the intraocular pressure (IOP) of the eye. The tonometer propels a small, plastic-tipped measurement probe in a controlled manner against a patient's unanesthetized eye in order to calculate IOP. The device has a simple, four-button control system and an LCD that provides information to the operator and displays measurement results.

There are two Tono-Vera Tonometer models:

• Tono-Vera Tonometer Starter Kit, AA Battery, Model 16305; and

• Tono-Vera Tonometer Starter Kit, Rechargeable, Model 16306.

Both models of the Tono-Vera Tonometer have a required accessory, the Ocu-Dot® Tonometer Probe, model 16318. The Ocu-Dot Tonometer Probe is a sterile, single-use, disposable accessory.

b. Device Features:

The Tono-Vera Tonometer utilizes a camera-based alignment system, called ActiView™ to improve alignment with the apex of the cornea and reduce measurement variability caused by operator technique. The measuring process starts automatically once alignment conditions are fulfilled.

The device has two measurement options: 3+ (Quick) Measurement Option and 6 Measurement Option. Both the 3+ (Quick) Measurement Option and 6 Measurement Option use the same calculation for the IOP result. The 3+ (Quick) Option can calculate a final IOP result with as few as three measurements. The 6 Measurement Option always uses six measurements to calculate the final IOP result.

The Tono-Vera Tonometer can be connected to a computer with ReichertSync® installed on it. Data from ReichertSync can be imported by an EMR system.

The Tono-Vera Tonometer determines IOP by detecting and analyzing the motion of the measurement probe as it briefly contacts the cornea.

c. Patient Contact: There are two direct patient contact points: the adjustable Flexi-Soft Forehead Rest which is used to stabilize the device during the measurement sequence and the Ocu-Dot Tonometer Probe which touches the patient's eye during the measurement sequence.

d. Use Environment: The Tono-Vera Tonometer is a prescription-only device. It is intended to be used by properly trained eye care professionals such as ophthalmologists, optometrists, opticians, and eye-care technicians. The device will be used in doctors' offices, clinics, and hospitals.

Intended Use/Indications for Use **21 CFR 807.92(a)(5)**

The Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes is intended to be used for the measurement of intraocular pressure of the human eye.

Indications for Use Comparison **21 CFR 807.92(a)(5)**

The Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes have the same intended use and Indications for Use as the Icare Ic100 (K153694). Both devices are intended to be used for the measurement of intraocular pressure (IOP) of the human eye. The Indications for Use of the Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes adopts the same language from the Indication for Use of the Icare Ic100 (K153694) in that both devices are intended to be used for the measurement of intraocular pressure of the human eye. Both devices have similar IOP measurement ranges and accuracy profiles. Both devices are similar in size, shape, and display function. The differences between the Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes and the Icare Ic100 (K153694), do not raise any different questions of safety and effectiveness as confirmed through the Performance Testing.

Technological Comparison **21 CFR 807.92(a)(6)**

The Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes (proposed device) and the Icare Ic100 (K153694) (predicate device) are highly similar in key safety and technological characteristics. Both devices use rebound technology to measure intraocular pressure (IOP). Both devices are active, microprocessor controlled, handheld devices that use a sterile, disposable, single-use probe to contact a patient's unanesthetized eye during the IOP measurement.

The bench test comparison for measurement accuracy and repeatability using proposed device and predicate device was performed to establish basis for substantial equivalence over the entire measurable

IOP range (5 to 60 mmHg) of the proposed device. The results for Pressure Range 5 to <20 mmHg showed the proposed device with Accuracy (±2 SD) of 0.49 and Repeatability (CV%) of 2.30% as compared to the predicate device with Accuracy (±2 SD) of 0.95 and Repeatability (CV%) of 6.30%. Whereas the results for Pressure Range >20 to 60 mmHg showed the proposed device with Accuracy (±2 SD) of 1.82 and Repeatability (CV%) of 2.00% as compared to the predicate device with Accuracy (±2 SD) of 2.57 and Repeatability (CV%) of 3.00%.

The Tono-Vera utilizes a camera-based alignment system, called ActiView, to improve alignment and reduce measurement variability associated with operator technique, whereas the predicate device is a manual device which does not have a comparable alignment system. However, the ActiView Auto Measure Mode can be disabled in the system menu and the operator can choose to take manual measurements instead.

The Tono-Vera has a Data Transfer feature where the IOP measurement results can be transferred via Bluetooth to an EMR system whereas the predicate has no Data Transfer capabilities.

Both the Tono-Vera Tonometer (Model 16305 (AA Battery)) and predicate device have the same power supply, 4 x 1.5V AA batteries. Whereas the second option of Tono-Vera Tonometer (Model 16306 (Rechargeable)) uses a 3.7V Li-ion rechargeable battery pack.

The Tono-Vera device has a measurement range of 5-60 mmHg (display range of 1-99 mmHg) and the predicate device has a measurement range of 7-50 mmHg (display range of 1-99 mmHg.). The predicate device uses six measurements to produce a single IOP result. Tono-Vera 6 Measurement Option also uses six measurements to produce a single IOP result. In addition, Tono-Vera has a second measurement option that can be selected by the operator. The Tono-Vera 3+ (Quick) Measurement option can produce an IOP result in as few as three measurements.

The devices are similar in Display, Weight, and Dimensions. The devices are similar in materials in that both use thermoplastic materials for the device housings and tonometer probe tip. There are minor differences in the Force applied to the eye during the rebound measurement and in the Device Orientation during use. The predicate has a wider range for force applied to the eye during measurement. The predicate device must be oriented roughly horizontally, whereas the Tono-Vera can be oriented horizontally within ± 15 degrees.

Overall, the Tono-Vera Tonometer and Ocu-Dot Tonometer Probes are substantially equivalent to the predicate device, Icare ic100 Tonometer. They share the same technological characteristics with regard to physical and measurement attributes. Reichert has performed comprehensive performance testing to demonstrate that the device meets all required specifications. The testing demonstrated that the technological differences between Tono-Vera Tonometer and Ocu-Dot Tonometer Probes and the Icare Ic100 (K153694) do not raise any different questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions **21 CFR 807.92(b)**

All necessary bench testing were conducted on the Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes to support a determination of substantial equivalence to the predicate device.

Non-Clinical Testing included:

- Performance Testing - Bench
- Electrical Safety and Electromagnetic Compatibility
- Biocompatibility Testing
- Sterilization Validation Testing
- Shelf-Life and Packaging Validation Testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes does not raise different questions of safety or effectiveness when compared to the predicate Icare Ic100 (K153694) Tonometer.

Reichert conducted a clinical study between May 2022 and August 2022. (National Clinical Trial Number NCT05345262). The primary endpoint of the study was to determine if the Reichert Tono-Vera® Tonometer is equivalent to the Goldmann Applanation Tonometer per the requirements of the ANSI Z80.10-2014 standard. The study was a prospective, cross-sectional, single-center, non-significant risk study. The results demonstrate that Reichert Tono-Vera® Tonometer is safe and effective at IOP tonometry measurements without the need for anesthesia per the requirements of the ANSI Z80.10-2014 standard.

The Tono-Vera® Tonometer and Ocu-Dot® Tonometer Probes are substantially equivalent to the predicate Icare Ic100 (K153694) Tonometer. The devices have the same intended use, similar indications for use, and both devices use rebound technology to measure intraocular pressure. The devices have similar IOP measurement ranges and accuracy profiles. They are similar in size, shape, and display function. The Clinical study results demonstrate that Tono-Vera is safe and effective at IOP tonometry measurements without the need for anesthesia per the requirements of the ANSI Z80.10-2014 standard.