December 14, 2018

Crystalvue Medical Corporation
Oliver Lin
Director of Quality Assurance
No. 116, Ln.956, Zhongshan Rd.,
Taoyuan Dist., Taoyuan City 33072
Taiwan

Re: K180820
Trade/Device Name: Tono Vue Non-Contact Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKX
Dated: November 2, 2018
Received: November 7, 2018

Dear Oliver Lin:

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 yours,

Bradley S. Cunningham -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*

K180820

Device Name

TonoVue Non-Contact Tonometer

Indications for Use *(Describe)*

The TonoVue is a non-contact tonometer that intended to measure the intra-ocular pressure of the eye in patients with less than 3 diopters of corneal astigmatism.

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.

510(k) Summary

Crystalvue Medical Corporation
TonoVue Non-Contact Tonometer

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

Submitter

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Device Information

Classification:	Class II
Trade Name:	TonoVue Non-Contact Tonometer
Common Name:	Non-Contact Tonometer
Classification Name:	Tonometer, AC-Powered
Product Code:	21 CFR § 886.1930

Predicate Devices

Trade Name: Canon Full Auto Tonometer TX-20.
Classification Name: HKX, Tonometer and accessories
510(k) Number: K111710

Intended Use

The TonoVue is a non-contact tonometer that is intended to measure the intraocular pressure of the human eye in vivo.

Indication for Use

The TonoVue is a non-contact tonometer that intended to measure the intra-ocular pressure of the eye in patients with less than 3 diopters of corneal astigmatism.

Device Description

TonoVue Tonometer is designed to non-contact tonometer (NCT) that measures the intraocular pressure (IOP) by delivering a soft air puff without contacting eyes directly. It's designed as a full auto-alignment and All-In-One desktop type medical device with built-in thermal line printer. The dimensions of whole device are about 500mm (H) x 260mm (W) x 500mm (L). The AC power input port and a USB port are set at the bottom side of the device, but the USB port only for engineering use.

Based on the Imbert-Fick principle, the IOP is calculated by dividing the amount of air pressure into the area of applanated surface. TonoVue utilizes a rapid air puff to apply force for flattening the cornea of human eye, and an advanced electro-optical system to monitor its deformation. The puff force increases until the cornea is applanated over the predetermined area and detected by the pressure sensor inside TonoVue, and the IOP can be calculated.

Safety

Electrical safety and EMC testing were conducted on the TonoVue device. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Effectiveness

TonoVue tonometer is in general comparable to the predicate devices, regarding the use, design and technical characteristics.

The result of clinical testing is also proved the effectiveness of TonoVue tonometer in clinical use is same as other products available on the market.

Substantial Equivalence

The TonoVue is substantially equivalent to the predicate devices: CANON Full Auto Tonometer TX-20 (K111710). It has the same intended use, technological characteristics, and principles of operation as its predicate devices. Bench and clinical testing demonstrate substantially equivalent performance to the predicates. Performance data demonstrate that the TonoVue is as safe and effective as the predicate devices. Thus, the TonoVue is substantially equivalent with Canon TX-20.

Performance Data

(a) Software Validation

The Software verification and validation testing were conducted and documentation was provided as recommended by FDA Guidance- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Application of risk management to medical devices to show the software used in the TonoVue Tonometer is conform the safety principles.

(b) Biocompatibility Testing

The Biocompatibility test evaluation for TonoVue non-contact tonometer was conducted in accordance with the ISO10993-1. The test result of biocompatibility test is complies the ISO 10993-1 standard.

(c) Bench Testing

According to the FDA guidance of Tonometers - Premarket Notification Submissions requirement, the bench testing is performed to evaluate the accuracy and reproducibility of the TonoVue.
According to the testing result of accuracy and reproducibility, its prove the TonoVue non-contact tonometer's IOP measurement result can meet our product's specification.

(d) Clinical Testing

This study is followed the requirement of ISO 8612:2009 Ophthalmic instruments-Tonometers, to test the validity of OCT Tonometer. This clinical testing of TonoVue non-contact tonometer was study the 120 patients with less than 3 diopters of corneal astigmatism.
The test result of the TonoVue non-contact tonometer is met the requirement of ISO 8612:2009:
No more than 5% of the paired differences between the reference tonometer reading and the test tonometer reading for each pressure range are greater than the tolerance ±5mmHg.
Thus, the test instrument should be feasible when use in clinical.

Conclusion

As described in this 510(k) Summary, comprehensive testing and

analysis was conducted on the TonoVue to ensure that the device is safe and effective for its intended use when used in accordance with its instructions for use.

The Performance Data demonstrate that TonoVue is as safe and effective as predicate device, Canon Full Auto Tonometer TX-20. Based on the information in this submission, the TonoVue has the same intended use, technological characteristics, and principles of operation as its predicate devices. Therefore, the TonoVue is substantially equivalent to the predicate device.