CATS Tonometer LLC
Paul Kramsky
Consultant
1517 N. Wilmot
Suite 143
Tucson, Arizona 85712

Re: K203850
Trade/Device Name: CATS®-D Tonometer Prism
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKY
Dated: May 4, 2021
Received: May 6, 2021

Dear Paul Kramsky:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203850

Device Name

CATS®-D Tonometer Prism

Indications for Use *(Describe)*

The CATS®-D Tonometer Prism is intended to be used with Goldmann type tonometers 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Summary for the CATS®-D Tonometer Prism

5.1 Submission Sponsor:

CATS Tonometer, LLC
1517 N. Wilmot, Suite 143
Tucson, Arizona 85712
Telephone: 520- 975-4550

5.2 Contact:

CATS Tonometer, LLC
1517 N. Wilmot, Suite 143
Tucson, Arizona 85712
Telephone: 520- 975-4550
Contact: Nannon Roosa, President
Email: nannon@catsiop.com

5.3 Date Prepared:

June 8, 2021

5.4 Device Name:

Trade/Proprietary Name:	CATS®-D Tonometer Prism
Classification Name:	Tonometer and Accessories
Product Code:	HKY
Regulation Number:	21 CFR 886.1930

5.5 Predicate Devices:

The CATS®-D Tonometer Prism is substantially equivalent in terms of intended use and technological characteristics to the CATS® Reusable Tonometer prism (K173904).

5.6 Device Description:

The CATS®-D Tonometer Prism is used as an optical image prism for Goldmann applanation style tonometers. It is made of PMMA, the corneal contact diameter is 6.5 mm and the total length of the prism is 30 mm.

5.7 Indications for Use:

The CATS® Tonometer Prism is intended to be used with Goldmann type tonometers for the measurement of intraocular pressure of the human eye.

5.8 Performance Data:

Design verification and sterilization validation and shelf-life testing were performed. Cytotoxicity (MEM Elution), Sensitization (Kligman Maximization Test), and Irritation (Intracutaneous irritation test) were performed per ISO 10993-5 and ISO 10993-10. The device was reported to be non-cytotoxic, non-sensitizing and non-irritating.

5.9 Substantial Equivalence:

The CATS®-D Tonometer Prism is substantially equivalent to the 510(k) cleared CATS® reusable prism with the exception being that the disposable prism is supplied with a sterilized detachable, which snaps on to the prism housing, whereas the 510(k) cleared reusable prism was connected to the body with adhesive. This change resulted in a very slight decrease in overall length of the prism, which does not affect the safety and effectiveness of the device. In addition, the packaging was changed to a cardboard box consisting of a PETG tray with Tyvek lid, and sterilization by Ethylene Oxide. The claim of substantial equivalence to the previously cleared CATS® Reusable Tonometer Prism (K173904) is supported by the following comparison of characteristics in Table 1 and non-clinical performance data. Therefore, the CATS®-D Tonometer Prism is substantially equivalent to the predicate device.

Table 1 - Comparison of CATS® Disposable and CATS® Reusable (Predicate) Tonometer Prisms

Characteristic	CATS®-D Tonometer Prism	CATS® Reusable Tonometer Prism (Predicate)
Overall length	28.75 mm	30.0 mm
Base diameter	10.9 mm	10.9 mm
Contact surface diameter	6.5 mm	7.0 mm
Bi-Prism diameter	6.0 mm	6.0 mm
Bi-Prism length	10.67 mm	10.67 mm
Applanation Diameter	3.29 ± 0.02	3.29 ± 0.02
Bi-prism angle	30 degrees	30 degrees
Index of refraction	1.4906	1.4906
Prism construction material	PMMA	PMMA
Prism component adhesive	Class 9	Class 9
Prism contact surface	Concave-convex contoured	Concave-convex contoured
Prism surface finish **Force to IOP conversion**	Optical polish 1.0g = 10mm Hg	Optical polish 1.0g = 10mm Hg
Prism tip	Detachable	Connected to body
Packaging	4 PETG trays w/Tyvek lids in cardboard box	Cardboard box
Sterilization	Ethylene Oxide	Non-sterile