

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 20 2013

A. Submitter Information

Submitter's Name: Ocular Therapeutix, Inc.
Address: 36 Crosby Drive, Suite 101
Bedford, MA 02451
Telephone: 781-628-8998
Fax: 781-494-6557
Contact Person: Eric Ankerud, Executive Vice President Clinical,
Regulatory, Quality
Date of Preparation: November 19, 2013

B. Subject Device

Trade Name: Ocular Force Gauge
Common/Usual Name: Ocular Force Gauge
Classification Name: 21 CFR 886.1930, Tonometer and accessories
Class: II
Product Code: HKY

C. Predicate Device Name(s): Ophthalmodynamometer (Pre-amendment device)

D. Indication for Use:

The Ocular Force Gauge is indicated for applying measured force to the surface of the eye.

E. Device Description:

The Ocular Force Gauge is a non-sterile, reusable, precision spring-scale manual instrument designed and manufactured to apply measured force to the surface of the eye. The hand held device has a smooth "foot" similar to the shape of the "foot" of an ophthalmodynamometer, an instrument used to apply and measure force on the ocular surface. The Ocular Force Gauge "foot" is the surface of the device that contacts the ocular surface.

F. Predicate Device(s) Reference:

The Ocular Force Gauge was shown to be substantially equivalent in intended use, principle of operation, and technological characteristics to the legally marketed predicate device, the Ophthalmodynamometer.

G. Performance Data:

In vitro preclinical tests were performed to verify and validate the safety and effectiveness of the Ocular Force Gauge and assure substantial equivalence to the predicate device. The Ocular Force Gauge and the Ophthalmodynamometer are both reusable, ophthalmic instruments manufactured from medical grade metal with equivalent operating principles and intended use.

A study evaluating and comparing the Ophthalmodynamometer to the Ocular Force Gauge was performed. Two bench top tests were used to evaluate and compare the foot surface and the ability to apply force for each device. The test samples were loaded one at a time into the lower jaws of an Instron and depressed into the anvil at a rate of 1.0 Inch/Minute. When the load cell reached a force of 1.0 ounce the test ended. The maximum load and extension were recorded, and the jaws returned to the starting position. The foot of each instrument was visually inspected to ensure a smooth surface with no defect or debris in between repetitions of the force testing. All samples met pre-determined specifications for both the foot surface and compressive force.

Ocular Therapeutix completed with passing results a confirmatory cytotoxicity test on the Ocular Force Gauge per ISO 10993-5, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity.

The Ocular Force Gauge is a reusable, manual ophthalmic instrument that is supplied non-sterile. A cleaning and sterilization validation was performed on the Ocular Force Gauge demonstrating the device is able to be sterilized by gravity steam sterilization (autoclave) to a sterility assurance level (SAL) of 1×10^{-6} .

H. Standards

The Ocular Force Gauge has been designed to comply with the following voluntary standards.

Standards Applicable to the Ocular Force Gauge

Standard	Title
ISO 17665-1:2006	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 10993-1:2009 & ISO 10993-1:2009/Cor 1: 2010 ISO 10993-5:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process Part 5: Tests for in vitro cytotoxicity
ISTA 1A 2001	ISTA Pre-shipment Testing Procedures – Combination Tests for Packaged Products Weighing 150 lbs. (68kg) or less

I. Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation, and overall technological characteristics, the Ocular Force Gauge is determined to be substantially equivalent to the existing legally marketed device, the Ophthalmodynamometer.



December 20, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ocular Therapeutix, Inc.
% Eric P. Ankerud, J.D.
Executive Vice President, Clinical, Regulatory and Quality
36 Crosby Drive, Suite 101
Bedford, MA 01730

Re: K132917

Trade/Device Name: Ocular Force Gauge
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKY
Dated: November 19, 2013
Received: November 20, 2013

Dear Mr. Ankerud:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kesia Y. Alexander -S

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

Indications for Use Statement

510(k) Number (if known): K132917

Device Name:

Ocular Force Gauge

Indications for Use:

The Ocular Force Gauge is indicated for applying measured force to the surface of the eye.

Prescription Use

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jan C. Callaway 
2013.12.12 13:14:47 -05'00'