December 6, 2019

Company Elamed
Mikhail Kuzin
Certification Engineer
Yelatma instrument-making enterprise
JSC 391351, 25 Janina St.
Yelatma, RU Ryazan region

Re: K190382
Trade/Device Name: Intraocular Pressure Tonometer EASYTON
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKX
Dated: October 29, 2019
Received: November 4, 2019

Dear Mikhail Kuzin:

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 control's 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,

for Tieuvi Nguyen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190382

Device Name
Easyton

Indications for Use *(Describe)*
The Tonometer Easyton is indicated for the measurement of intraocular pressure in human eyes.

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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Yelatma Instrument Making Enterprise, JSC
25 Yanin st., Yelatma, Ryazan region, 391351, Russia. Tel./fax: +007 49131 / 2-04-57, 2-21-09, 4-38-29

510(k) Summary Complying with 21 CFR 807.9

I. SUBMITTER

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II. DEVICE

Name of Device: Intraocular Pressure Tonometer EASYTON
Common or Usual Name: tonometer, ac-powered
Regulation: 886.1930
Regulatory Class: II
Product Code: HKX

III. PREDICATE DEVICE

Diaton, K060780
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Device Description

A. Principles of Operation

Measurement Method

The principle of EASYTON measurement is based on simultaneous use of the two types of measuring actions – static and dynamic. Both actions are carried out by the vibrator's rod on the eyelid.

Static action is carried out during the time of measurement and determined by the weight of the vibrator.

Dynamic exposure represents itself during the vibrating action with frequency: about 150 HZ and amplitude: the millimeter hundredth parts and tactile is felt as soft vibration. Vibrator's rod is elastically movable in its axial direction and is set in oscillatory motion by electromagnetic way. While carrying out the measurement, the rod is put up on the eyelid, sagging (pressing the eyelid down with its weight about 10g and is fixed on sclera or an eye cornea forming elastic system of eye-vibrator with total mechanical rigidity. This system is disturbed from the equilibrium state by the rod's short term electromagnetic removal. In a system within tan equilibrium state restoration there are arising free damped vibration.

Functional connection between elastic system rigidity and the period of is own vibration is known. This period is measured by the tonometer and is used for IOP calculation being shown on the display.

EASYTON measures only the intraocular pressure.

Operating principle of the tonometer.

Fig. 1
Schematic representation of the tonometer rod movements.

When the EASYTON rod is placed on the eyelid and slightly pressed on the device, the rod slightly plunges into the device, and the generation of a measuring vibration effect begins.

This is schematically shown in Figure 1.

The vibration frequency of the "rod-eye" depends on the IOP.

The higher the IOP, the greater the vibration frequency.

The device registers the vibration frequency, recalculates it into the IOP value and displays it on its indicator.

Technical Specifications

Specification	Value
Measuring range of IOP, mmHg	7 to 50
Limits of permissible absolute error of measurement: From 7 to 23 mm Hg More than 23 mm Hg	 +/- 2 +/- 5
Measurement time (sec)	2
Repeatability (coefficient of variation), %	≤8,1
applanation area, contact area, or area of corneal deformation	None
type of pressure transducer (e.g., optical detector, strain gauge) and specifications	Inductive
Power supply: Number of elements x voltage, V Type of battery Power supply voltage, V Current consumption in measurement mode, mA, not more	 2 x 1,5 AAA 2 - 3,3 100
Display Data output	LCD Display
data storage capability (e.g., measurement results, patient information)	Store of last measurement result until power off
interface with other equipment (e.g., printer, computer network)	None
dimensions (L x H x W) mm, not more	173 x 27 x 21
weight (g)	88
Operating temperature range, C (need F) Relative air humidity, %, not more Atmospheric pressure, kPa	+10 to +35 80 84 to 106.7

V. INDICATIONS FOR USE

The Tonometer Easyton is indicated for the measurement of intraocular pressure in human eyes.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Intraocular Pressure Tonometer EASYTON	DIATON	Substantially Equivalent or Different
Indications for Use	The Tonometer Easyton is indicated for the measurement of intraocular	The Diaton Tonometer is intended to measure intraocular pressure (IOP). The device is	Substantially Equivalent

	pressure in human eyes.	intended for use as an aid in the diagnosis of glaucoma and for monitoring IOP.	
Classification	product code HKY (regulation number 886.1930)	product code HKY (regulation number 886.1930)	Substantially Equivalent
Materials	Biocompatible patient contacting materials	Biocompatible patient contacting materials	Substantially Equivalent
Sterilization method	not sterilized	not sterilized	Substantially Equivalent
Technological Characteristics:			
Measurement on base	Goldman	Maklakov	**Different**
Measurement range (Hg)	from 7 to 50	from 5 to 60	Substantially Equivalent
Time of single measurement (sec)	2	3	Substantially Equivalent
Power supply type and voltage	1,5 V AAA x2	1,5 V AAA x2	Substantially Equivalent
Size/dimensions (mm)	173 x 27 x 21	174 x 26 x 20	Substantially Equivalent
Weight	88 g	89 g	Substantially Equivalent
Features:			
No direct affect on the cornea	Yes	Yes	Substantially Equivalent
Portability	Yes	Yes	Substantially Equivalent
Displays independent from corneas crookedness	Yes	Yes	Substantially Equivalent
Digital IOP Indication	Yes	Yes	Substantially Equivalent
Short time measurement	Yes	Yes	Substantially Equivalent
Sterilization is not required	Yes	Yes	Substantially Equivalent
Anesthesia is not required	Yes	Yes	Substantially Equivalent

Discussion of substantial equivalence

The indications for use, features, materials and technical parameters (with the exception of the measurement method) are either the same or substantially equivalent to each other. The difference between the two devices are the measurement methods. The difference in the measurement method does not impact safety or effectiveness

All tonometers are known to take IOP measurements indirectly, by measuring the response of the eye coats to a mechanical measuring stimulus.

The main feature of transpalpebral tonometry is the damping effect of the eyelid. The effect is balanced out by compressing the eyelid before the procedure, in the same manner as an eyelid is compressed (pushed against) by fingers before palpation.

The operating principle of DIATON is based on elastic interaction of the freely falling rod with the eyeball through eyelid.

Interaction of the rod with eyeball is the only part that is essential. The duration of this contact is less than 0.1 sec. The mechanical interference (movement of the eye, tremor of the operator's hand, etc.) in this fraction of time has a significant

impact on the measurement result, which is a defect common for all dynamic pulse methods of measurement.
Meanwhile, EASYTON enables a measuring process of a different kind. In this case, the eyelid is compressed before the measurement is started, and remains in this compressed state up until the measurement completion. The measuring process implies continuous active interaction of the rod with the eyeball (average time of contact is 1 sec.).

The amplitude of the free vibrations is of minor importance: it is the frequency that counts, which depends on the mass of the rod and the rigidity of the eye (IOP). Stability of the result is obtained by filtering 10-20 measuring periods produced during one measurement cycle.

Thus, the measuring method provided by EASYTON successfully combines the advantages of both static and dynamic methods.

The measuring action of EASYTON, just as that of DIATON, is exerted through eyelid in the scleral area corresponding to *corona ciliaris* in the meridian of 12 hours, and is perceived as mild vibration. No anesthesia is required prior to the measurement, which is taken in one second.

In addition, an improved method of disinfection with Rapicide RA raster registered in the US market was analyzed and laboratory confirmed.

Reference (comparative) studies were carried out on the measurement of IOP with the Tonometer Easyton and Tonometer Goldman in accordance with the requirements of ANSI Z80.I0-2014 (ISO 8612) on eyes of representative groups that take into account options for the anatomical features of the eyelids. Studies were conducted on representatives of:
–with low stiffness of the eyelids, in the Glaucoma Community of Russia, IPO (Moscow, Russia);
–with epicanthus, in the Regional Medical Center (Karaganda, Kazakhstan) and TENSV Clinic, LLP (Karaganda, Kazakhstan);
- with the stiffness rigidity of the eyelids, in Hospital Park (Gurgaon, New Delhi, India).
The study showed that the results of measurements with the tonometer Easyton and the Goldman tonometer are in the acceptable ranges of measurement error (no more than ± 5%) for all types of eyes examined.

Based on the above comparisons we have determined that the difference in measuring does not impact safety or effectiveness. Therefore we conclude that the subject device and predicate device are substantially equivalent.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

We have assessed all of our patient contacting materials for biocompatibility requirements in accordance with the May 1, 1995 FDA Biocompatibility Guidance, the FDA-modified matrix of the "International Standard ISO-10993", "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", including the flow chart entitled "Biocompatibility Flow Chart for the Selection of Toxicity Tests of 510(k)'s.

We have determined that the patient contacting portion of the device is a body surface contacting device for less than 24 hours.

The patient contacting materials are:

Tonometer stock made of Alloy D16 complies with requirements of GOST 21488-97 with a chemical composition according to GOST 4784 and there is a chance of contact Tonometer ring made of BRAZH9-4 complies with requirements of GOST 1628-78 with chemical composition according to GOST 18175.- working part tonometer (1).

Additionally, an investigation was carried out on non-contacting parts of the Tonometer to completely eliminate hazards. ABS RESIN HI-121– cover, case (2).

The device passed all biocompatibility tests.

Validation of Cleaning and Sterization Methods

The device is not sterilized. Infection measures are analyzed of investigation relating to the validation process.
Disinfection instructions for the buffer ring and of the rod is included in the owner's manual. These parts are reusable.

Electrical safety and EMC testing were conducted on the complies with:
the IEC 60601-1, IEC 60601-2-2 standards for safety and the IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8, CISPR 11 standards for EMC.

Software Verification

The software level of concern for this device type is moderate based on the answers to the questions in the guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

Clinical Performance

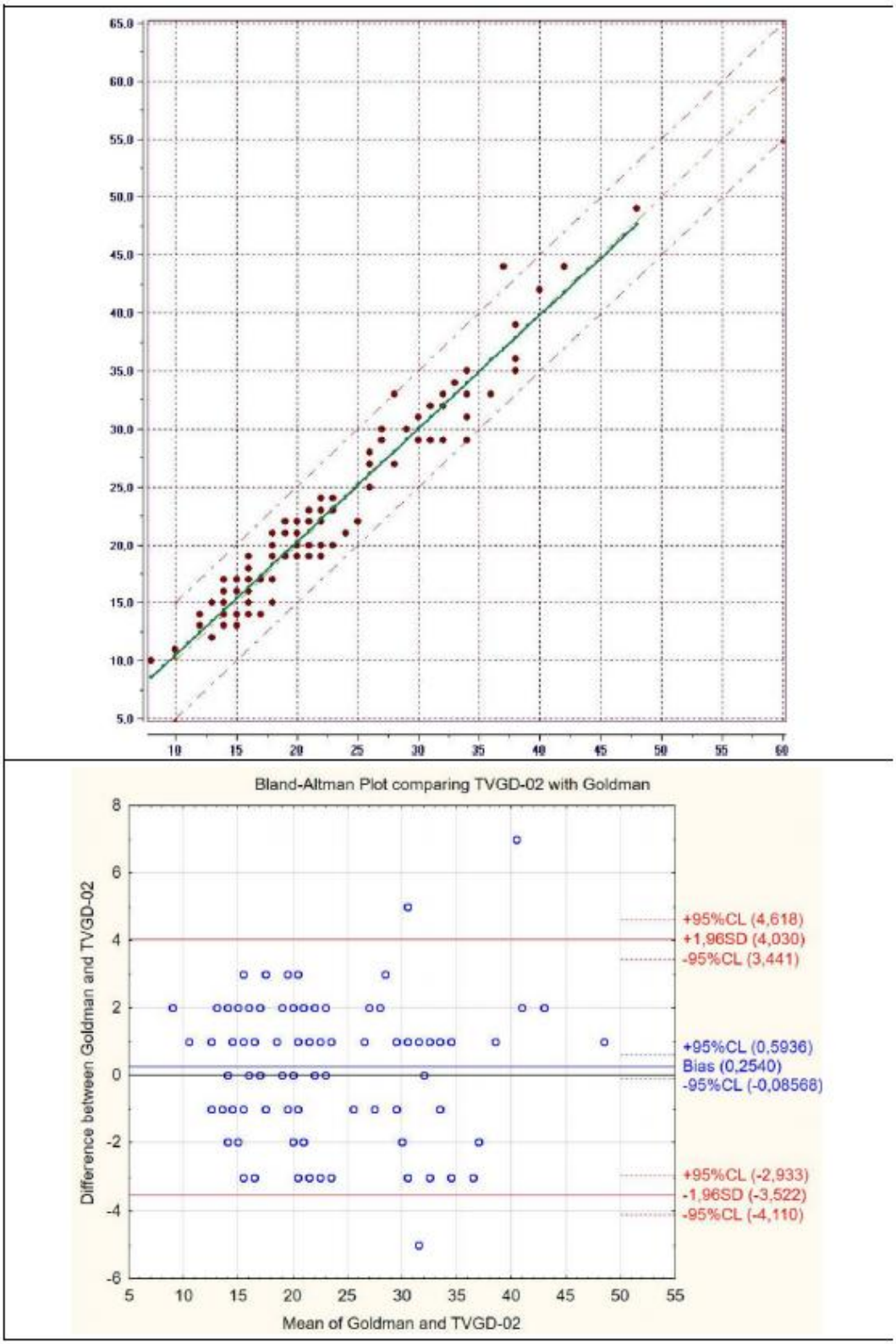
To account for anatomical differences of eyelid structures in the indicated patient population, three comparative studies were carried out for measurements of IOP using the Easyton and Goldmann Applanation Tonometers. All three studies were conducted in accordance with the requirements of ANSI Z80.10-2014 and two of the studies included additional measurements of high astigmatic eyes. Brief descriptions and results of these comparative studies are provided below:

1) “Low stiffness eyelids study”. In this study we enrolled a Caucasian population with low stiffness of the eyelids. The study was conducted in the Glaucoma Community of Russia, IPO (Moscow, Russia). The study was conducted in 156 patients (eyes) distributed in 3 IOP ranges, as follows:

IOP Range	**#of eyes (≤3D Cyl)**	**#of eyes (>3D Cyl)**
7 to 16	46	10
>16 to <23	40	10
≥23	40	10

The comparative study results are shown in the following graphs:

Appendix 1. The regression and Bland-Altman graphs studies for representatives with low stiffness of the eyelids.

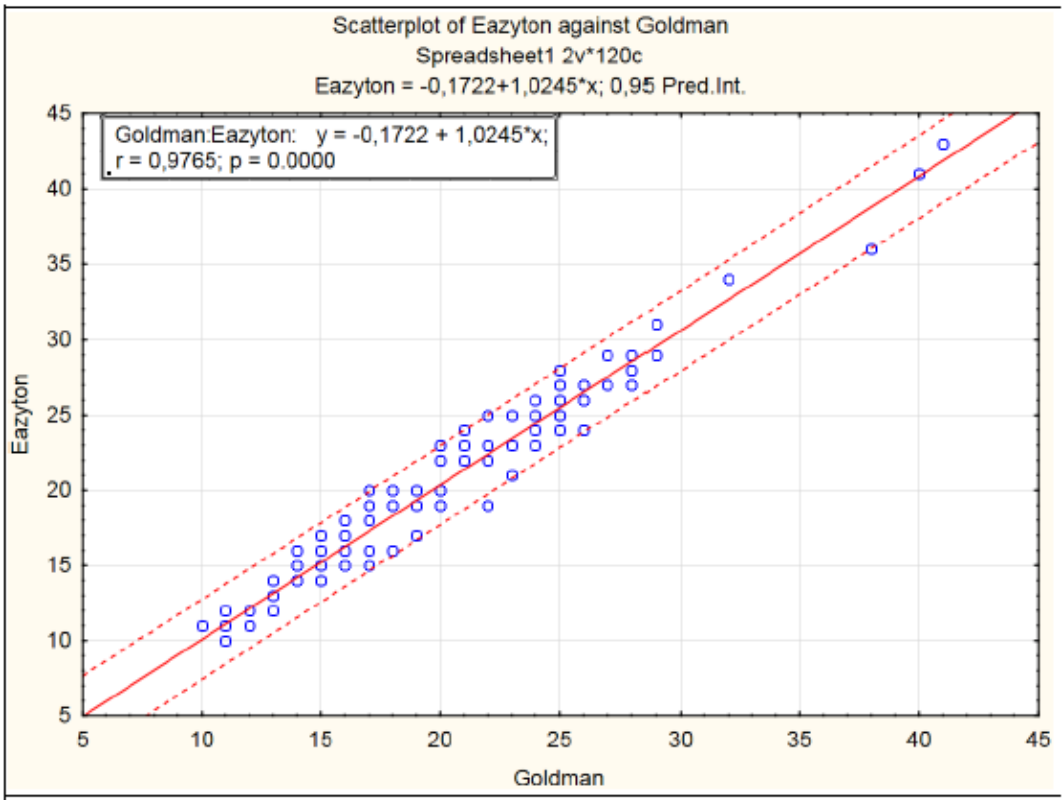


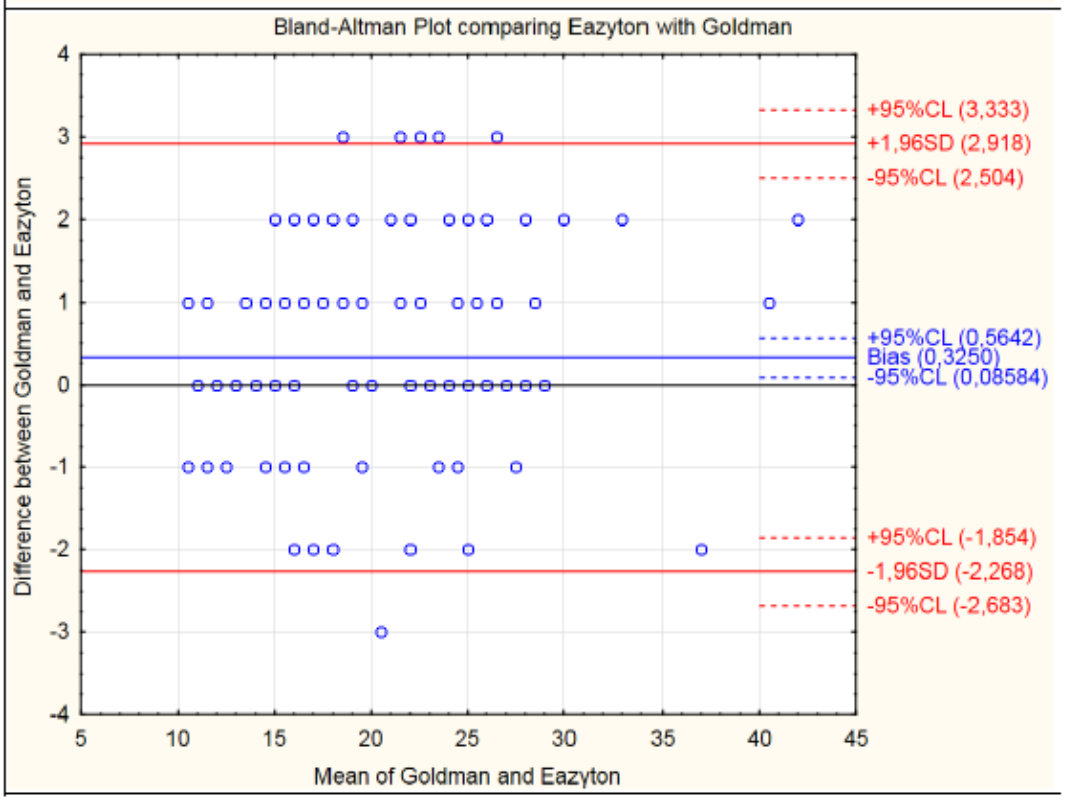
2) “Epicanthus study”. In this study we enrolled an Asian population with epicanthal fold of the eyelid. The study was conducted in Regional Medical Center (Karaganda, Kazakhstan) and TENSV Clinic, LLP (Karaganda, Kazakhstan). The study was conducted in 150 patients (eyes) distributed in 3 IOP ranges, as follows

IOP Range	**#of eyes (≤3D Cyl)**	**#of eyes (>3D Cyl)**
7 to 16	40	10
>16 to <23	40	10
≥23	40	10

The results of the “Epicanthus” comparative study are shown in the following graphs:

Appendix 2. The regression and Bland-Altman graphs studies for representatives with epicanthus.



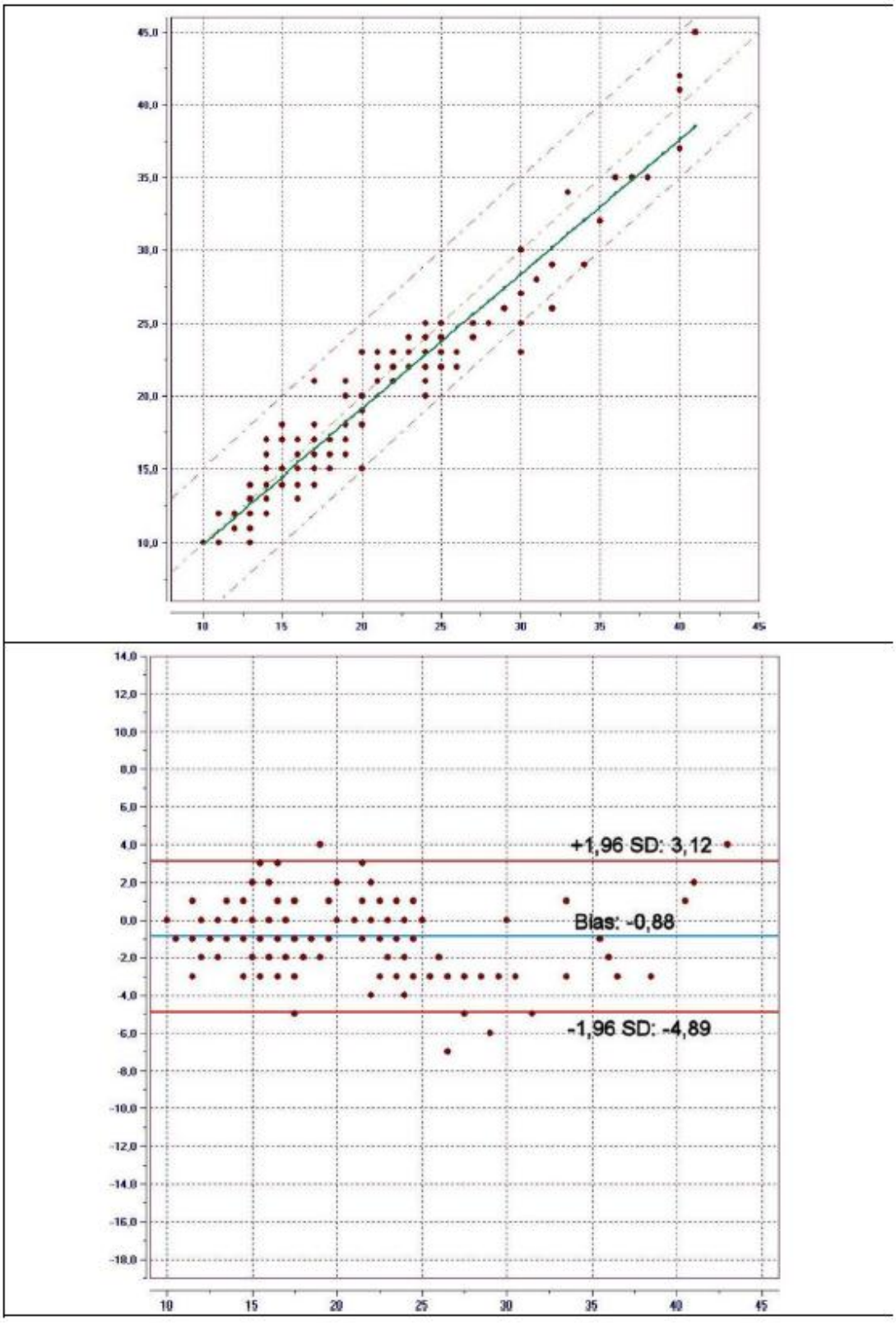


3. “Rigid stiffness eyelids study”. In this study we enrolled an Indian population with rigid stiffness of eyelids. The study was conducted in Hospital Park (Gurgaon, New Delhi, India). The study was conducted in 78 patients (155) distributed in 3 IOP ranges, as follows:

IOP Range	**#of eyes (≤3D Cyl)**
7 to 16	53
>16 to <23	60
≥23	42

The results of the “Rigid stiffness eyelids” comparative study are shown in the following graphs:

Appendix 3. The regression and Bland-Altman graphs studies for representatives with the stiffness stiffness of the eyelids



The table below shows the summary of all three comparative studies:

Comparison Study	Main Group			Astigmatic Group		
	Bias	Slope	±1.96 SD	Bias	Slope	±1.96 SD
Russia (Caucasian, thin eyelids)	-0.25 mmHg	0.978	±3.78 mmHg	+0.83 mmHg	1.035	±3.13 mmHg
Kazakhstan (Asian, fatty eyelids)	+0.32 mmHg	1.02	±2.59 mmHg	+0.77 mmHg	0.948	±2.10 mmHg
India (stiff eyelids)	-0.88 mmHg	0.923	±4.01 mmHg			

Subjects with the rigid eyelids have a larger scatter of values and a lower correlation coefficient. This suggests that the biomechanical characteristics and anatomical features of the eyelid influence the IOP measurement result. However, it should be noted that this does not significantly affect the measurement results. The results from all three the studies showed that for all type of tested eyelids requirements of Z80.10-2014 are met, because not 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 for that range.

It can be concluded that IOP measurements by the tonometer «EASYTON» correspond to the declared accuracy for all representative groups that take into account options for the anatomical features of the eyelids.

VIII. CONCLUSIONS

Substantial equivalence comparison and bench performance tests support the conclusion of substantial equivalence of the Easyton Tonometer to the predicate device.