



November 7, 2025

Topcon Corporation  
% Lena Sattler  
President  
Orasi Consulting, LLC.  
226 1st Street  
Bonita Springs, Florida 34134

Re: K253039

Trade/Device Name: AUTO KERATO-REFRACTO TONOMETER TRK-3 OMNIA  
Regulation Number: 21 CFR 886.1930  
Regulation Name: Tonometer And Accessories  
Regulatory Class: Class II  
Product Code: HKX, MXK  
Dated: September 22, 2025  
Received: September 22, 2025

Dear Lena Sattler:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Alexander Beylin -S** Date: 2025.11.07 11:50:07  
-05'00'

for 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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253039

?

Please provide the device trade name(s).

?

AUTO KERATO-REFRACTO TONOMETER TRK-3 OMNIA

Please provide your Indications for Use below.

?

TRK-3 OMNIA is a combination of the non-contact tonometer and pachymeter. The device is indicated for automatic measurement of intraocular pressure without contacting the eye (with less than 3 diopters of corneal astigmatism); and measurement of central corneal thickness.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

## **510(k) SUMMARY**

### **Traditional 510(k) K253039**

#### **TOPCON CORPORATION AUTO KERATO-REFRACTO TONOMETER TRK-3 OMNIA**

#### **GENERAL INFORMATION**

##### **Submitter's information:**

TOPCON Corporation  
75-1 Hasunuma-cho, Itabashi-ku  
Tokyo, 174-8580, Japan

##### **Contact person:**

Lena Sattler  
President, Orasi Consulting, LLC.  
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##### **Date Prepared:**

September 22, 2025

#### **DEVICE INFORMATION**

##### **SUBJECT DEVICE**

**Name of Device:** AUTO KERATO-REFRACTO TONOMETER  
TRK-3 OMNIA  
**Classification:** Class II  
**Classification Name:** 21 CFR 886.1930 (Tonometer and accessories)

**Primary Product Code:** HKX (Tonometer, Ac-Powered)

**Secondary product Codes** MXK (Device, Analysis, Anterior Segment)

**PRIMARY PREDICATE DEVICE**

**Company:** TonoVue Non-Contact Tonometer  
**Device:** Crystalvue Medical Corporation  
**510(k) No.:** K180820  
**Classification Name:** 21 CFR §886.1930 (Tonometer and accessories)  
**Product Code:** HKX (Tonometer, Ac-Powered)

**SECONDARY PREDICATE DEVICE**

**Company:** TOPCON CORPORATION  
**Device:** SP-1P Specular Microscope  
**510(k) No.:** K142417  
**Classification Name:** 21 CFR §886.1850 (AC Powered Slit Lamp Biomicroscope)  
**Product Code:** NQE (Microscope, Specular)

**BRIEF DEVICE DESCRIPTION**

TRK-3 OMNIA is a multiple function device, a combination of the auto refractometer, keratometer, non-contact tonometer, and pachymeter. The device is capable of automatic measurement of the refractive errors of the eye; measurement of the corneal curvature of the eye; measurement of intraocular pressure without contacting the eye (with less than 3 diopters of corneal astigmatism); and measurement of central corneal thickness. The device also calculates corneal diameter and pupil distance.

**INTENDED USE / INDICATIONS FOR USE**

TRK-3 OMNIA is a combination of the non-contact tonometer and pachymeter. The device is indicated for automatic measurement of intraocular pressure without contacting the eye (with less than 3 diopters of corneal astigmatism); and measurement of central corneal thickness.

**NON-CLINICAL TEST RESULTS**

Non-clinical evaluation and testing results according to the following standards and the FDA's guidance documents were submitted. TRK-3 OMNIA satisfied the requirements.

- ISO 10993-1
- IEC 60601-1-2
- IEC 60601-1
- ISO 8612
- "7. Bench Testing" of the FDA's guidance document, "*Tonometers – Premarket Notification [510(k)] Submissions*"
- The FDA's Guidance document "*Content of Premarket Submissions for Device Software Functions*" (issued on June 14, 2023)

## **CLINICAL TEST RESULTS**

### **1. Clinical Study for Tonometer Function**

A prospective clinical study was conducted, at a U.S. clinical site, to confirm that the tonometer function of the TRK-3 OMNIA conforms to the tonometry standards, ISO 8612:2009 and ANSI Z80.10-2014 (except for the requirement for "highly astigmatic eyes (>3 D of corneal astigmatism)" in B5.3 of Annex B). "8.Clinical Performance" of the FDA guidance document, "Tonometers - Premarket Notification [510(k)] Submissions (issued on March 27, 2006) and the Extent of Recognition in the FDA Supplementary Information Sheet (FR Recognition List Number 040, FR Recognition Number 10-96, Date of Entry 08/14/2015) were also taken into consideration.

The sample size was at least 120 eyes from 120 subjects, including at least 40 eyes in each of the categories of low IOP (7-16 mmHg), intermediate IOP (>16 mmHg to <23 mmHg), and high IOP (>23 mmHg) and at least 2 eyes with IOP of 30 mmHg or higher. Eligibility criteria were defined by tonometer standards, and included participants aged 22 years or older, with the main exclusion criteria being those with corneal scarring, corneal surgery including corneal laser surgery, keratoconus, and central corneal thickness greater than 0.6 mm or less than 0.5 mm, and corneal astigmatism greater than 3D.

A total of 125 subjects were enrolled in the study and 120 subjects completed the study with all valid measurements. **Table A** shows the demographics.

**Table A: Demographics**

<b>Parameter</b>	<b>Low IOP (7 to 16 mmHg) (N=40)</b>	<b>Intermediate IOP (&gt; 16 to &lt; 23) (N=40)</b>	<b>High IOP (≥ 23) (N=40)</b>	<b>Total (N=120)</b>
<b>Age (Years)</b>				
N	40	40	40	120
Mean (SD)	50.9 (14.7)	56.0 (13.6)	62.2 (11.2)	56.4 (13.9)
Median	55	57	65	59
(Min, Max)	(24, 71)	(27, 80)	(25, 85)	(24, 85)
<b>Age Range</b>				
22 - 30 years	15.0% (6/40)	2.5% (1/40)	2.5% (1/40)	6.7% (8/120)
31 - 40 years	12.5% (5/40)	12.5% (5/40)	2.5% (1/40)	9.2% (11/120)
41 - 50 years	12.5% (5/40)	22.5% (9/40)	2.5% (1/40)	12.5% (15/120)
51 - 60 years	25.0% (10/40)	22.5% (9/40)	30.0% (12/40)	25.8% (31/120)
61 - 70 years	32.5% (13/40)	20.0% (8/40)	37.5% (15/40)	30.0% (36/120)
>70 years	2.5% (1/40)	20.0% (8/40)	25.0% (10/40)	15.8% (19/120)
<b>Sex</b>				
Male	45.0% (18/40)	45.0% (18/40)	37.5% (15/40)	42.5% (51/120)
Female	55.0% (22/40)	55.0% (22/40)	62.5% (25/40)	57.5% (69/120)
<b>Race</b>				
American Indian Or Alaska Native	2.5% (1/40)	7.5% (3/40)	0.0% (0/40)	3.3% (4/120)
Asian	10.0% (4/40)	5.0% (2/40)	5.0% (2/40)	6.7% (8/120)
Black Or African American	7.5% (3/40)	22.5% (9/40)	75.0% (30/40)	35.0% (42/120)
Hawaiian Or Other Pacific Islander	5.0% (2/40)	2.5% (1/40)	0.0% (0/40)	2.5% (3/120)
White	75.0% (30/40)	60.0% (24/40)	20.0% (8/40)	51.7% (62/120)
Not Disclosed	0.0% (0/40)	2.5% (1/40)	0.0% (0/40)	0.8% (1/120)
<b>Ethnicity</b>				
Hispanic Or Latino	17.5% (7/40)	12.5% (5/40)	2.5% (1/40)	10.8% (13/120)

**Table A: Demographics**

Parameter	Low IOP (7 to 16 mmHg) (N=40)	Intermediate IOP (> 16 to < 23) (N=40)	High IOP (≥ 23) (N=40)	Total (N=120)
Not Hispanic Or Latino	82.5% (33/40)	85.0% (34/40)	97.5% (39/40)	88.3% (106/120)
Not Disclosed	0.0% (0/40)	2.5% (1/40)	0.0% (0/40)	0.8% (1/120)
<b>Study Eye</b>				
OD	55.0% (22/40)	57.5% (23/40)	40.0% (16/40)	50.8% (61/120)
OS	45.0% (18/40)	42.5% (17/40)	60.0% (24/40)	49.2% (59/120)

The IOP between the test tonometer TRK-3 OMNIA and the reference tonometer (Goldmann Applanation Tonometer) in eyes without high corneal astigmatism was compared over the three IOP ranges and there was no study eye with IOP exceeding the tolerance of paired differences ( $\pm 5.0$  mmHg) in all IOP ranges, as shown in **Table B**.

**Table B: Summary of the tonometer study**

IOP range (mmHg)		Number of study eyes	Number of eyes within the tolerance of paired differences	Number of eyes outside the acceptable range (%)		Mean and Standard deviation of differences between TRK-3 and GAT (mmHg)
Low IOP	7 to 16	40	40	0	(0.0)	2.10 (1.68)
Intermediate IOP	>16 to <23	40	40	0	(0.0)	-0.20 (1.40)
High IOP	≥23	40	40	0	(0.0)	-2.45 (1.81)

The TRK-3 OMNIA conforms to all the requirements of ISO 8612:2009 and ANSI Z80.10-2014 (except for the requirement for "highly astigmatic eyes (>3 D of corneal astigmatism)" in B5.3 of Annex B). For the safety evaluation, no subjects experienced adverse events in this study.

## 2. Clinical Study for Pachymeter Function

Topcon conducted a prospective comparative clinical study, at a U.S. clinical site, to compare the agreement and precision of the pachymeter function between TRK-3 OMNIA and SP-1P Specular Microscope (K142417). Participants age 22 years or older were enrolled and assigned to one of three groups: 1) “Normal Cornea”, 2) “Abnormal Cornea”, and 3) “Glaucoma”. The sample size was 30 eyes of 30 subjects for each group. Key enrollment criteria for 2) were to include at least one eye with corneal abnormality, to include (but not limited to) corneal transplants, abnormal corneal shape, long term (>3 years) daily contact lens use, post keratorefractive surgery and dry eye. Key enrollment criteria for 3) were to include eyes with visual field defect(s) consistent with glaucomatous optic nerve damage.

A total of 108 subjects were consented and 105 subjects were enrolled in the study; 90 subjects completed the study with valid pachymetry readings (central corneal thickness, CCT, in micron), 30 subjects in each study group. **Table C** shows the demographics.

**Table C: Demographics**

	<b>Normal Cornea</b>	<b>Abnormal Cornea</b>	<b>Glaucoma</b>
	<b>Total</b>	<b>Total</b>	<b>Total</b>
	<b>(N=30)</b>	<b>(N=30)</b>	<b>(N=30)</b>
<b>Age (years)</b>			
N	30	30	30
Mean(SD)	40.0 (14.8)	44.2 (17.6)	64.9 (8.9)
Min, Max	24, 69	24, 82	45, 82
Median	36.5	40	66
<b>Age Range</b>			
22 - 30 years	12 (40.00%)	9 (30.00%)	0 (0.00%)
31 - 40 years	4 (13.33%)	6 (20.00%)	0 (0.00%)
41 - 50 years	6 (20.00%)	5 (16.67%)	3 (10.00%)
51 - 60 years	4 (13.33%)	3 (10.00%)	6 (20.00%)
61 - 70 years	4 (13.33%)	4 (13.33%)	14 (46.67%)
>70 years	0 (0.00%)	3 (10.00%)	7 (23.33%)

	<b>Normal Cornea</b>	<b>Abnormal Cornea</b>	<b>Glaucoma</b>
	<b>Total</b>	<b>Total</b>	<b>Total</b>
	<b>(N=30)</b>	<b>(N=30)</b>	<b>(N=30)</b>
<b>Sex</b>			
Male	8 (26.67%)	4 (13.33%)	14 (46.67%)
Female	22 (73.33%)	26 (86.67%)	16 (53.33%)
<b>Race</b>			
Asian	5 (16.67%)	6 (20.00%)	1 (3.33%)
Black or African American	3 (10.00%)	10 (33.33%)	25 (83.33%)
Not Disclosed	1 (3.33%)	0 (0.00%)	1 (3.33%)
White	20 (66.67%)	12 (40.00%)	3 (10.00%)
White, Asian	1 (3.33%)	2 (6.67%)	0 (0.00%)
<b>Ethnicity</b>			
Hispanic or Latino	7 (23.33%)	2 (6.67%)	3 (10.00%)
Not Disclosed	0 (0.00%)	0 (0.00%)	1 (3.33%)
Not Hispanic or Latino	23 (76.67%)	28 (93.33%)	26 (86.67%)

Of the abnormal cornea eyes tested in this study, all 30 had clinically significant slit lamp cornea findings. 3 (10.0%) had corneal transplants, 6 (20.0%) had various abnormal corneal shapes including 2 (6.7%) scarring, 10 (33.3%) had long term daily contact lens use, 8 (26.6%) had a form of post keratorefractive surgery, and 1 (3.3%) had corneal ring. All 30 eyes were CXL, 7 (23.3%) had dry eye, 1 (3.3%) had opacity, 1 (3.3%) had Guttata, and 1 (3.3%) had Pterygium.

Agreement between TRK-3 OMNIA and SP-1P was evaluated by the mean difference and corresponding standard deviation, the 95% LOA, Bland-Altman plots, and the Deming regression for each subject population. A summary of the agreement study is provided in **Table D**.

**Table D: Summary of agreement of CCT between TRK-3 OMNIA and SP-1P**

<b>TRK-3 OMNIA Mean (SD)</b>	<b>SP-1P Mean (SD)</b>	<b>Mean Difference (SD)</b>	<b>95% Limits of Agreement</b>	<b>Correlation (R<sup>2</sup>)</b>
<b>Normal Cornea (N=30)</b>				
533.7 (34.68)	533.6 (34.35)	0.1 (6.12)	(-11.9, 12.1)	0.969
<b>Abnormal Cornea (N=30)</b>				
512.8 (50.17)	516.7 (46.64)	-4 (9.32)	(-22.2, 14.3)	0.969
<b>Glaucoma (N=30)</b>				
500.4 (24.18)	501.2 (23.05)	-0.8 (6.82)	(-14.2, 12.6)	0.92

The analysis of precision used a two-way random-effect ANOVA model to estimate the repeatability and reproducibility limits, and coefficient of variation of CCT by subject population and study device. A summary of the precision study is provided in **Table E**.

**Table E: Summary of precision of CCT between TRK-3 OMNIA and SP-1P**

	CCT	TRK-3 OMNIA	SP-1P
<b>Normal Cornea (N=30)</b>	Overall Mean	533.5	533.5
	Repeatability SD	2.405	7.402
	Repeatability SD as % of the Mean	0.45%	1.39%
	Repeatability Limit	6.735	20.726
	Repeatability Ratio	0.325 (2.405 / 7.402)	
	Reproducibility SD	3.318	7.69
	Reproducibility SD as % of the Mean	0.62%	1.44%
	Reproducibility Limit	9.291	21.533
	Reproducibility Ratio	0.431 (3.318 / 7.690)	
<b>Abnormal Cornea (N=30)</b>	Overall Mean	513.7	515.7
	Repeatability SD	2.83	10.799
	Repeatability SD as % of the Mean	0.55%	2.09%
	Repeatability Limit	7.925	30.236
	Repeatability Ratio	0.262 (2.830 / 10.799)	
	Reproducibility SD	3.762	10.826
	Reproducibility SD as % of the Mean	0.73%	2.10%
	Reproducibility Limit	10.533	30.313
	Reproducibility Ratio	0.347 (3.762 / 10.826)	
<b>Glaucoma (N=30)</b>	Overall Mean	499	501
	Repeatability SD	3.384	4.895
	Repeatability SD as % of the Mean	0.68%	0.98%
	Repeatability Limit	9.475	13.705

	CCT	TRK-3 OMNIA	SP-1P
	Repeatability Ratio	0.691 (3.384 / 4.895)	
	Reproducibility SD	4.411	4.937
	Reproducibility SD as % of the Mean	0.88%	0.99%
	Reproducibility Limit	12.351	13.825
	Reproducibility Ratio	0.893 (4.411 / 4.937)	

As shown in the table above, the repeatability SD and reproducibility SD of TRK-3 for all three groups are less than those of SP-1P (both the repeatability ratio and reproducibility ratio are less than 1), indicating that the variability of TRK-3 is less than that of SP-1P.

The overall results of agreement and precision analysis support the substantial equivalence of TRK-3 OMNIA to SP-1P. For the safety evaluation, no subjects experienced adverse events in this study.

#### **SUBSTANTIAL EQUIVALENCE**

The subject device, the TRK-3 OMNIA, is substantially equivalent to the predicate devices because the intended use/indications for use, operation principle and technological characteristics of the TRK-3 OMNIA are similar or equivalent to those of the predicate devices as shown in **Table F** and **Table G** in the following pages.

The TRK-3 OMNIA has functions subject to FDA premarket review (the non-contact tonometer, and pachymeter functions) as well as functions that are not subject to FDA premarket review (the refractometer, keratometer functions). For the functions that are not subject to FDA premarket review (the refractometer, keratometer functions), FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

**Table F: Substantial Equivalence – TRK-3 OMNIA and TonoVue for Tonometry**

<b>Model Number</b>	<b>TRK-3 OMNIA (Subject device)</b>	<b>TonoVue (Predicate device)</b>	<b>Substantial Equivalence Discussion</b>
<b>Trade Name</b>	AUTO KERATO-REFRACTO-TONOMETER TRK-3 OMNIA	TonoVue Non-Contact Tonometer	N/A
<b>510(k) submitter/holder</b>	TOPCON Corporation	Crystalvue Medical Corporation	N/A
<b>510(k) Number</b>	N/A	K180820	N/A
<b>Product code</b>	HKX (Tonometer, Ac-Powered) MXK (Device, Analysis, Anterior Segment)	HKX (Tonometer, Ac-Powered)	Equivalent
<b>Regulation No.</b>	21 CFR 886.1930 (Tonometer and accessories) 21 CFR 886.1850 (AC-Powered Slitlamp Biomicroscope)	21 CFR 886.1930 (Tonometer and accessories)	Equivalent
<b>Product class</b>	II	II	Equivalent
<b>Intended Use /Indications for Use</b>	TRK-3 OMNIA is a combination of the non-contact tonometer and pachymeter. The device is indicated for automatic measurement of intraocular pressure without contacting the eye (with less than 3 diopters of corneal astigmatism); and measurement of central corneal thickness.	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.	Equivalent
<b>Operating principle</b>	The light source (LED) for applanation detection incorporated in the measuring head emits luminous flux for applanation detection and project it onto the cornea. The measuring nozzle of the intraocular pressure measuring window blows air onto the cornea. The applanation sensor incorporated in the measuring head detects that a certain area of the cornea becomes planar by the air. Then, the pressure sensor incorporated in the measuring head detects the amount of pressure required to flatten the certain area of the cornea. The instrument software installed in the measuring head performs arithmetic processing based on the detected amount of	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. 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.	Equivalent

Traditional 510(k) TRK-3 OMNIA  
Topcon Corporation

Model Number	TRK-3 OMNIA (Subject device)	TonoVue (Predicate device)	Substantial Equivalence Discussion
	pressure and calculates the intraocular pressure value.		
<b>Technological Characteristics</b>	Measuring range of intraocular pressure: 7 mmHg to 60 mmHg	Measuring range of intraocular pressure: 1– 60 mmHg	Similar
<b>Conformity Standards</b>	<ul style="list-style-type: none"> <li>• ISO 10993-1</li> <li>• IEC 60601-1-2</li> <li>• IEC 60601-1</li> <li>• ISO 8612</li> <li>• “Bench Testing” of the FDA’s guidance document, “Tonometers - Premarket Notification [510(k)] Submissions”</li> </ul>	<ul style="list-style-type: none"> <li>• ISO 10993-1</li> <li>• IEC 60601-1-2</li> <li>• IEC 60601-1</li> <li>• ISO 8612</li> <li>• “Bench Testing” of the FDA’s guidance document, “Tonometers - Premarket Notification [510(k)] Submissions”</li> </ul>	Equivalent

**Table G: Substantial Equivalence – TRK-3 OMNIA and SP-1P for Pachymetry**

<b>Model Number</b>	<b>TRK-3 OMNIA (Subject device)</b>	<b>SP-1P (Predicate device)</b>	<b>Substantial Equivalence Discussion</b>
<b>Trade Name</b>	AUTO KERATO-REFRACTO- TONOMETER TRK-3 OMNIA	SP-1P Specular Microscope	N/A
<b>510(k) submitter/holder</b>	TOPCON Corporation	TOPCON Corporation	Same
<b>510(k) Number</b>	N/A	K142417	N/A
<b>Product code</b>	HKX (Tonometer, Ac-Powered) MXK (Device, Analysis, Anterior Segment)	NQE (Microscope, Specular)	Similar
<b>Regulation No.</b>	21 CFR 886.1930 (Tonometer and accessories) 21 CFR 886.1850 (AC-Powered Slitlamp Biomicroscope)	21 CFR 886.1850 (AC- Powered Slitlamp Biomicroscope)	Equivalent
<b>Product class</b>	II	II	Equivalent
<b>Intended Use /Indications for Use</b>	TRK-3 OMNIA is a combination of the non-contact tonometer and pachymeter. The device is indicated for automatic measurement of intraocular pressure without contacting the eye (with less than 3 diopters of corneal astigmatism); and measurement of central corneal thickness.	The Specular Microscope SP- 1P is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of corneal endothelium and for measurement of the thickness of the cornea.	Equivalent
<b>Operating principle</b>	The light source (LED) for pachymetry measurement incorporated in the measuring head emits slit light and projects it onto the cornea obliquely. The line sensor incorporated in the measuring head receives the reflected lights from the front and back surfaces of the cornea. The instrument software installed in the measuring head performs arithmetic processing based on the received lights and calculates the central corneal thickness.	The slit light is projected onto the patient eye at a slant. The corneal thickness is measured by processing reflected light from the corneal surface and back, which is received by line sensor that is optically installed in a diagonal.	Equivalent

Model Number	TRK-3 OMNIA (Subject device)	SP-IP (Predicate device)	Substantial Equivalence Discussion
<b>Technological Characteristics</b>	Measuring range of the corneal thickness 0.400 mm to 0.730 mm	Measuring range of the corneal thickness 0.400-0.750mm	Similar

### **CONCLUSION**

The results of the non-clinical tests and clinical tests demonstrate that TRK-3 OMNIA is as safe, as effective, and performs as well as the legally marketed devices, and that TRK-3 OMNIA is substantially equivalent to the predicate devices.