January 19, 2018

Tomey Corporation
% Ryan Bouchard, Official Correspondent
Ora, Inc.
300 Brickstone Square
Andover, MA 01810

Re: K171313
Trade/Device Name: EM-4000 Specular Microscope
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: December 17, 2017
Received: December 19, 2017

Dear Ryan Bouchard:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Bradley S. Cunningham -S

for Malvina 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)*

K171313

Device Name
EM-4000 Specular Microscopy

Indications for Use *(Describe)*

The EM-4000 Specular Microscope is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

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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510(k) Summary

This summary of the 510(k) premarket notification for the Tomey EM-4000 Specular Microscope is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

Date Prepared: January 12, 2018

SPONSER/ 510(k) OWNER/ MANUFACTURER

Tomey Corporation
2-11-33 Noritakeshinmachi
Nishi-ku, Nagoya 451-0051
JAPAN

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NAME OF DEVICE

Trade Name: EM-4000 Specular Microscope
Common Name: Specular Microscope

DEVICE CLASSIFICATION/FDA REVIEWING BRANCH

The Ophthalmic Branch has classified AC Powered Slit Lamp Biomicroscopes as Class II devices pursuant to 21 C.F.R. §886.1850.

PRODUCT CODE: CLASSIFICATION / CFR TITLE

NQE, 21 CFR 886.1850

PREDICATE DEVICES

Konan Medical, Inc. Cellchek XL (K120264)

INDICATIONS FOR USE

The EM-4000 Specular Microscope is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

PRODUCT DESCRIPTION

The Tomey EM-4000 Specular Microscope is a non-contact ophthalmic microscope and camera intended for corneal endothelium imaging. Its operating principle is based on the Specular optical principle. This device is used for imaging the corneal endothelium. The EM-4000 analyzes and displays data such as cell number, cell density, coefficient of variation and percent hexagonality. When photographing the corneal endothelium, the equipment performs the alignment and automatically focuses by capturing the reflected light from the patient's eye with the CCD camera. Infrared LEDs are used as the light source for the alignment. Operation with the joystick also makes it possible to focus manually. The green LED light radiates to the cornea, and the endothelium image is captured with the CCD camera by the reflected light from the cornea. The endothelium images are stored in internal memory.

Furthermore, the EM-4000 is able to measure the central corneal thickness. The corneal endothelium is photographed first followed by measuring the central corneal thickness. The infrared LED light for measurement of corneal thickness radiates to the cornea through the objective lens for photographing the cornea, and the central corneal thickness can be calculated by measuring the distance on the optical line sensor between the reflected light from front surface and back surface of cornea.

SUBSTANTIAL EQUIVALENCE

The Tomey EM-4000 Specular Microscope is substantially equivalent to the Konan Medical, Inc. Cellchek XL (K120264). The Tomey EM-4000 Specular Microscope has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicate device. The Tomey EM-4000 Specular Microscope and the predicate device are both non-contact ophthalmic microscopes, optical pachymeters, and cameras intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

The EM-4000 and the Konan Cellchek XL both utilize the general specular optical principle for imaging endothelial cells and performing pachymetry. The two devices use different light sources for measurement and focusing. However, compliance with ISO 15004-2 is documented. The EM-4000 uses a green LED for measurement and an infrared LED for focusing while the predicate device uses a Xe tube flash lamp for measurement and halogen lamp for focusing.

Both devices measure cell number, cell density, coefficient of variation and percent hexagonality. The clinical performance data demonstrates the substantial equivalence of the EM-4000 to the Konan predicate device. Both the EM-4000 and the Konan Cellchek XL include an optical pachymeter with an accuracy of ± 10 microns. Bench testing comparing the EM-4000 pachymetry functionality to the predicate device is provided. The non-clinical and clinical performance data demonstrated the substantial equivalence of the pachymetry measurements. For the measurements assessed, the Tomey EM-4000 Specular Microscope and predicate device results were found to be substantially equivalent.

NON-CLINICAL PERFORMANCE SUMMARY

The performance testing conducted using the EM-4000 verified that the device operates as intended. The pachymetry functionality was evaluated and the measurement accuracy of ± 10 microns was confirmed.

Additionally, the EM-4000 was subjected to electrical safety testing in accordance with ANSI/AAMI ES60601-1, electromagnetic compatibility (EMC) testing in accordance with IEC 60601-1-2, and optical radiation safety testing in accordance with ISO 15004-1 and ISO 15004-2.

CLINICAL PERFORMANCE SUMMARY

A prospective clinical study was conducted to assess the agreement, accuracy and precision of the EM-4000 by comparing results across three machines/operators to those obtained with the predicate device, the Konan Cellchek XL. Three populations were studied: young (18-28 years of age) and adult (29-80 years of age) healthy subjects and pathologic adult eyes (29-80 years of age).

There were 70 subjects enrolled in the study: 25 in the non-pathologic young eye population, 23 in the non-pathologic adult eye population, and 22 in the pathologic adult eye population. Of those, 67 were included in the effectiveness population for the agreement portion of the study for the specular microscope variables. For the central corneal thickness (CCT) variable, 68 subjects were included in the effectiveness population.

Of the 70 enrolled subjects, 44 were included in the population for the precision portion of the study: 14 in the non-pathologic young eye population, 15 in the non-pathologic adult eye population, and 15 in the pathologic adult eye population.

The agreement and variability of the analysis methods was obtained using a sample that included virtually no eyes with predicate device measurements of

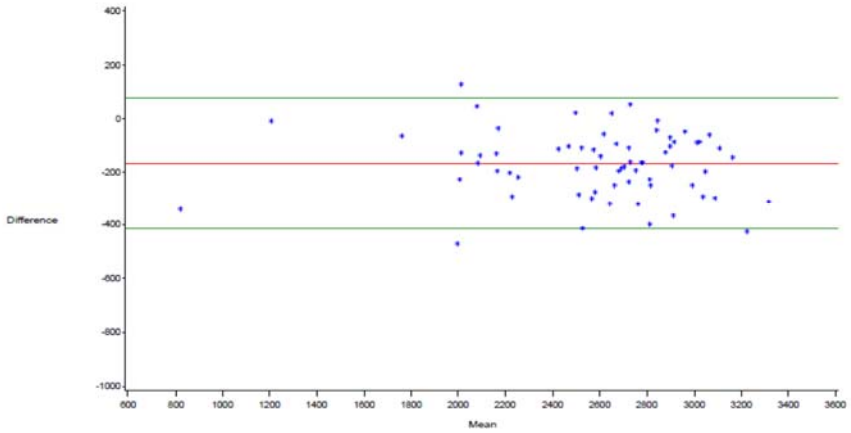
Percent Hexagonality <45, Coefficient of Variation >0.40, or Cell Density <1900. Agreement and variability of the analysis methods is not known for eyes with parameters beyond these values.

The clinical study results for the device measurements using the Core Method of analysis were based upon the use of a reading center

Endothelial Cell Density

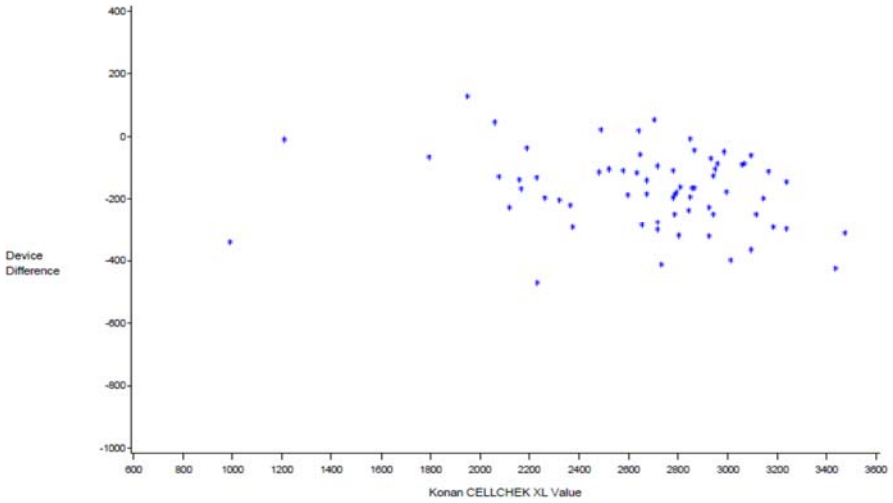
For the Core Method, the mean difference for endothelial cell density (CD) was -6.49%. . The mean differences for endothelial cell density are illustrated on the Bland Altman plot (Figure 1). Plots of the device differences by the CellChek XL value are presented (Figure 2). The Deming regression lines showed an associated correlation value of 0.9634 (Figure 3). Table 1 provides a summary of the agreement data for all subjects with the Core Method.

Figure 1 Bland-Altman Plot − Observed Data − Endothelial Cell Density (CD) – Core Method- All Subjects − Effectiveness Population



Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs). The differences are calculated as (Tomey EM-4000) - (Konan CellChek XL).

Figure 2 Device Difference by Konan CellChek XL Value − Endothelial Cell Density (CD) – Core Method-All Subjects − Effectiveness Population



The differences are calculated as (Tomey EM-4000) - (Konan CellChek XL).

Figure 3 Deming Regression Plot – Tomey EM-4000 by Konan CellChek XL − Endothelial Cell Density (CD) – Core Method - All Subjects − Effectiveness Population

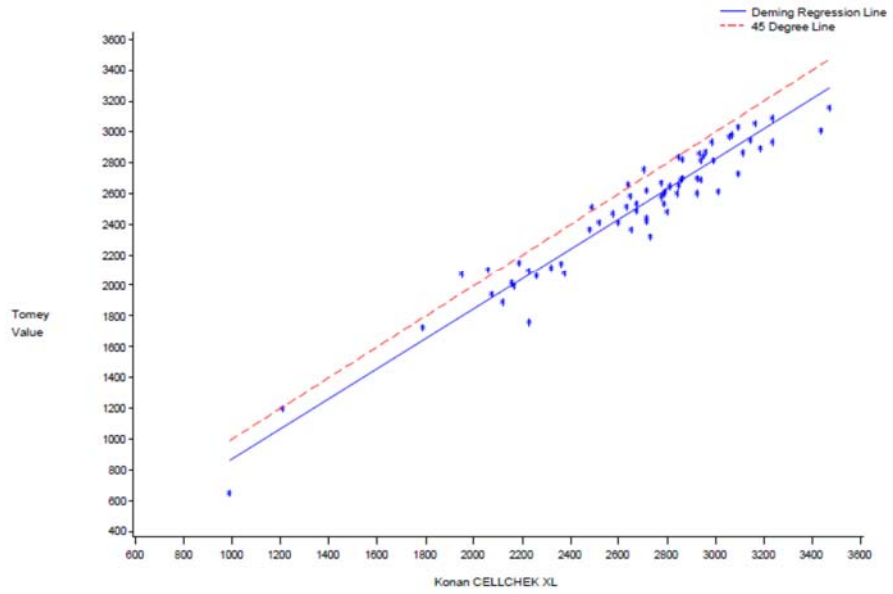


Table 1 Core Method: Corneal Specular Microscopic Variables Assessed with the Two Devices – All Configurations − All Subjects − Effectiveness Population

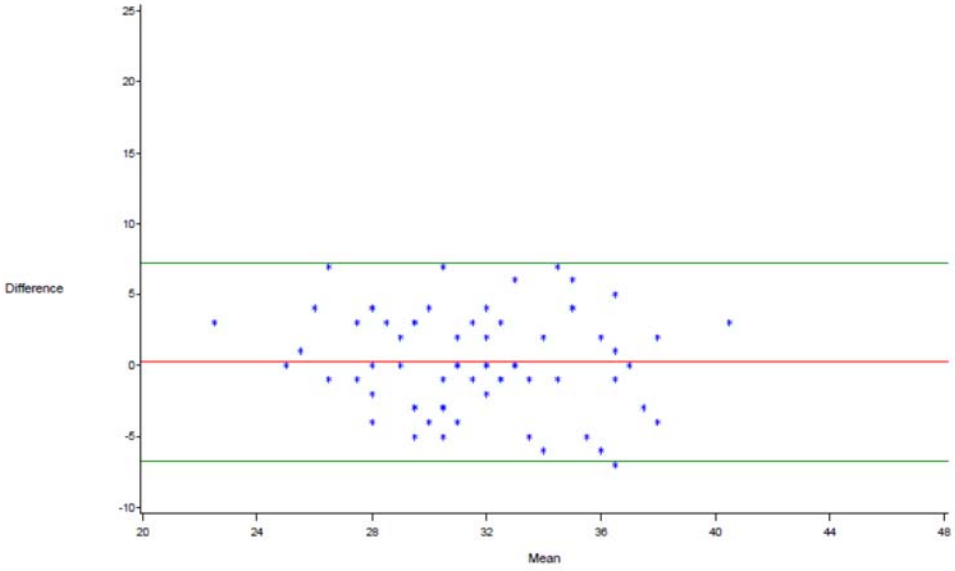
	CD	CV	% HEX	CCT
Tomey Specular Microscope EM-4000				
N	67	67	67	68
Mean (SD)	2504.6 (443.68)	31.8 (3.83)	60.3 (6.54)	542.1 (41.88)
Median	2604.0	31.0	60.0	543.5
Min-Max	650-3161	24-42	41-77	416 - 644
Konan CellChek XL				
N	67	67	67	67
Mean (SD)	2674.3 (454.08)	31.5 (4.18)	60.8 (8.61)	559.9 (42.25)
Median	2778.0	32.0	60.0	560.5
Min- Max	990-3472	21-40	33-80	441 - 677
Device Comparisons				
Mean Difference (SD)	-169.7 (121.95)	0.3 (3.49)	-0.4 (7.38)	-17.8 (22.57)
Mean Difference (SD) as a % of the CellChek reading	-6.49% (5.648%)	1.65% (11.304%)	0.70% (15.091%)	-3.11% (3.995%)
95% LOA	(-413.6, 74.2)	(-6.7, 7.3)	(-15.2, 14.3)	(-62.9, 27.4)
Correlation (R)	0.9634	0.6226	0.5549	0.8561
Deming Regression Intercept (95% CI)	-106.1 (-387.7, 175.4)	4.4 (-4.0, 12.8)	22.9 (2.5, 43.3)	66.9 (-3.8, 137.6)
Deming Regression Slope (95% CI)	1.0 (0.9, 1.1)	0.9 (0.6, 1.1)	0.6 (0.3, 0.9)	1.0 (0.9, 1.1)

Abbreviations: CD = endothelial cell density; CI = confidence interval; CV = coefficient of variation of endothelial cell area; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation
For subjects in the Precision and Agreement cohort, the measurements from the first acceptable images from each machine within the same configuration are used for the agreement analyses.
The mean differences are calculated as (Tomey Specular Microscope EM-4000) - (Konan CellChek XL).
The mean differences as a % of the CellChek reading are calculated for each subject first and then summarized.

Coefficient of Variation (CV) of Endothelial Cell Area

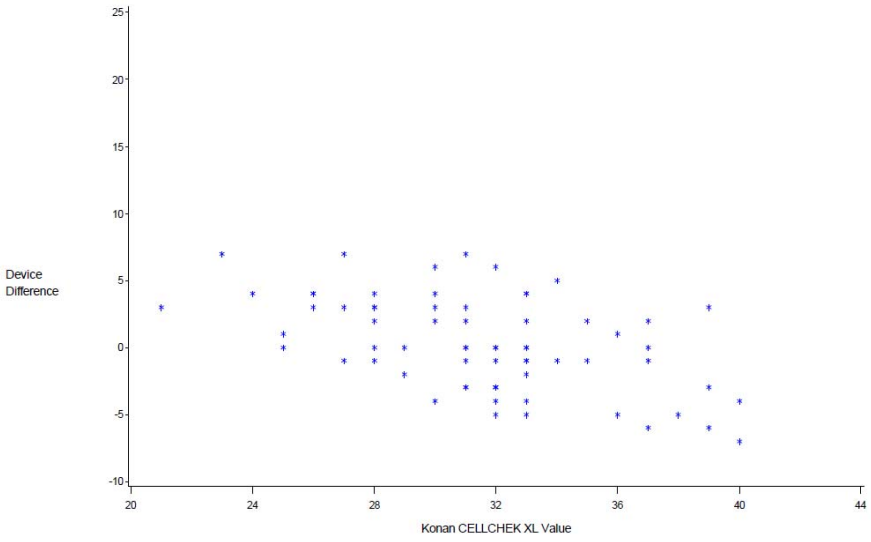
For the Core Method, for all configurations and all subjects, the Tomey EM-4000 mean (SD) difference, as illustrated on the Bland Altman plots (Figure 4) was 1.65% (SD 11.304%). Plots of the device difference by the CellChek XL value are presented in (Figure 5). The Deming regression lines showed an associated value of 0.6226 (Figure 6).

Figure 4 Bland-Altman Plot − Observed Data – Coefficient of Variation Endothelial Cell Area (CV) – Core Method - All Subjects − Effectiveness Population



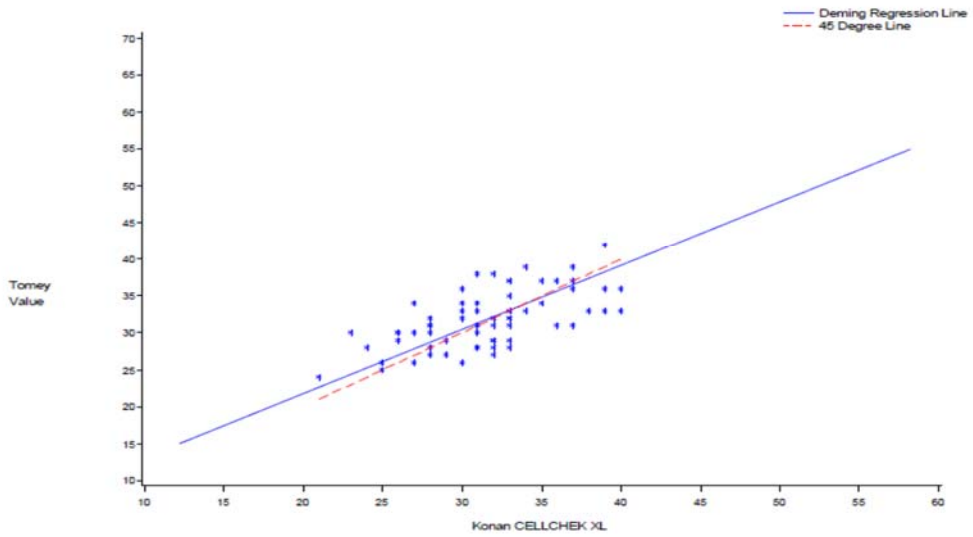
Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs). The differences are calculated as (Tomey EM-4000) - (Konan CellChek XL).

Figure 5 Device Difference by Konan CellChek XL Value − Coefficient of Variation Endothelial Cell Area (CV) – Core Method - All Subjects − Effectiveness Population



The differences are calculated as (Tomey EM-4000) - (Konan CellChek XL).

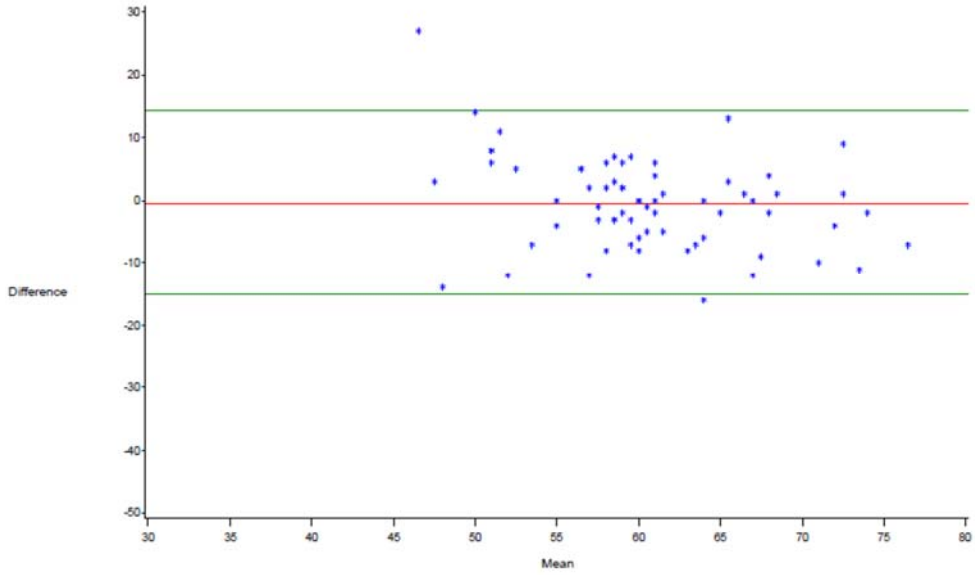
Figure 6 Deming Regression Plot – Tomey EM-4000 by Konan CellChek XL − Coefficient of Variation Endothelial Cell Area (CV) – Core Method - All Subjects − Effectiveness Population



Percent Hexagonality

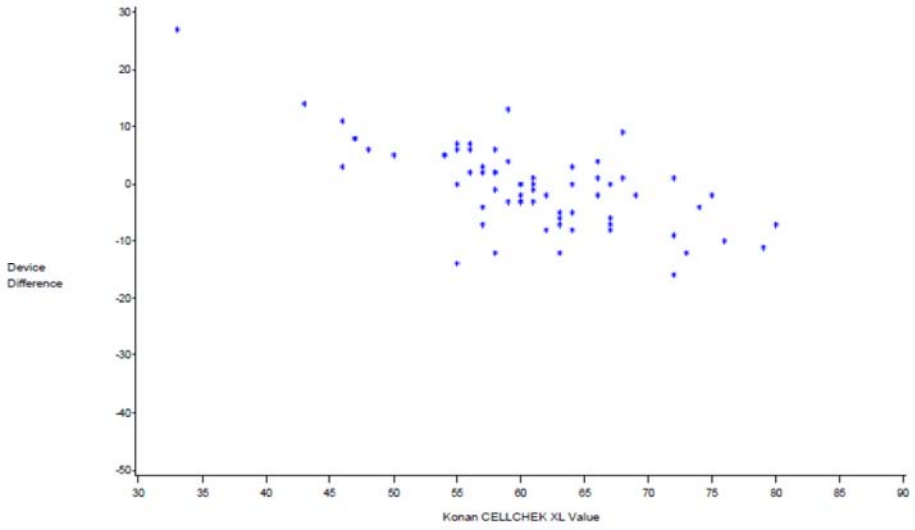
For the Core Method, for all configurations and all subjects, the Tomey EM-4000 mean (SD) % HEX compared to the CellChek XL was 0.70% (SD 15.091%). Bland Altman plots with data as a percentage of the mean are presented in Figure 7. Plots of the device difference by the CellChek XL value are presented in Figure 8. The Deming regression lines showed an associated correlation value of 0.5549 (Figure 9).

Figure 7 Bland-Altman Plot − Observed Data – % Hexagonality (HEX) – Core Method - All Subjects − Effectiveness Population



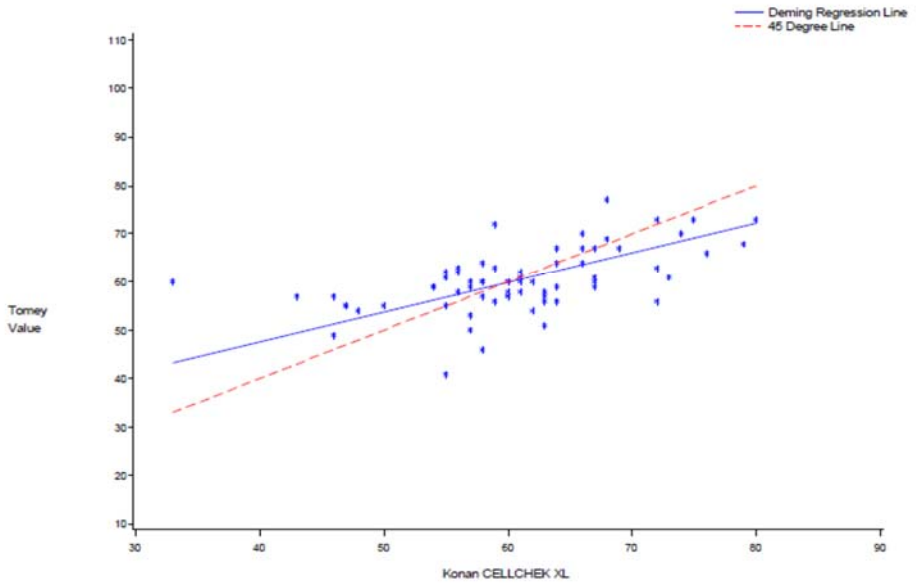
Note: The red line is the mean and the green lines are the Limits of Agreement (LOAs). The differences are calculated as (Tomey EM-4000) - (Konan CellChek XL).

Figure 8 Device Difference by CellChek XL Value − % Hexagonality – Core Method - All Subjects − Effectiveness Population



The differences are calculated as (Tomey EM-4000) - (Konan CellChek XL).

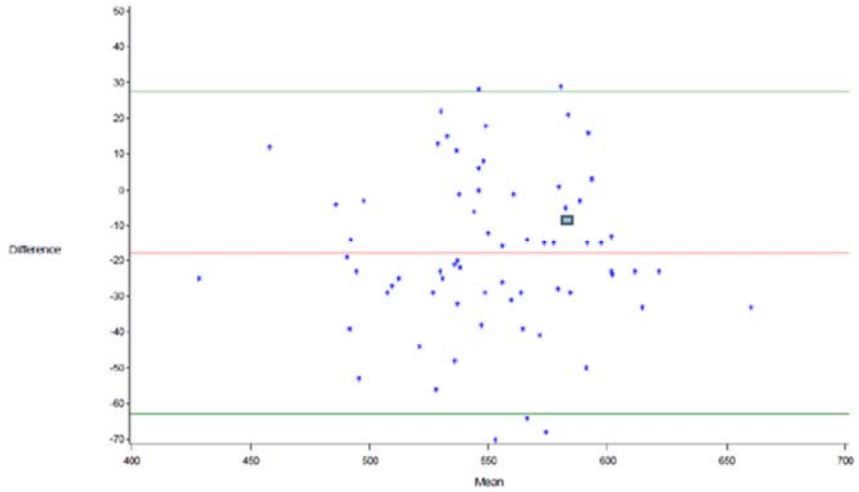
Figure 9 Deming Regression Plot – Tomey EM-4000 by Konan CellChek XL − % Hexagonality (HEX) – Core Method - All Subjects − Effectiveness Population



Central Corneal Thickness

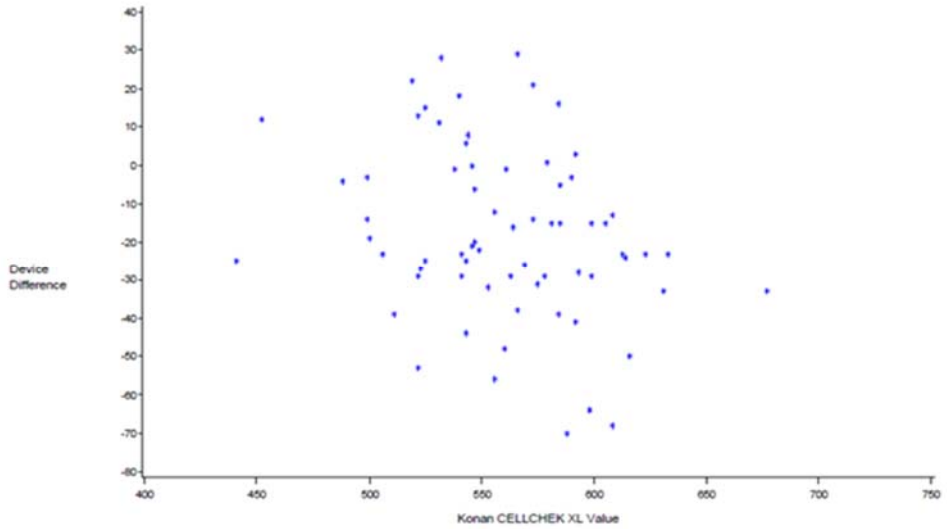
For the Core Method, for all configurations and all subjects, the Tomey EM-4000 mean (SD) CCT compared to the CellChek XL was -3.11% (SD 3.995%). Bland Altman plots with data as a percentage of the mean are presented in Figure 10. Plots of the device difference by the CellChek XL value are presented in Figure 11. The Deming regression lines showed an associated correlation value of 0.8561 (Figure 12).

Figure 10 Bland-Altman Plot – Observable Data – Central Corneal Thickness (CCT) – Core Method – All Subjects – Effectiveness Population



Note: The red line is the mean and the green lines are the LOAs. The differences are calculated as (Tomey EM-4000) – (Konan CellChek XL)

Figure 11 Device Difference by CellCheck XL Value – Central Corneal Thickness (CCT) – Core Method – All Subject – Effectiveness Population.



The differences are calculated as (Tomey EM-4000) – (Konan CellChek XL)

Figure 12 Deming Regression Plot – Tomey EM-4000 by Konan CellChek XL – Central Corneal Thickness (CCT) – Core Method – All Subjects – Effectiveness Population

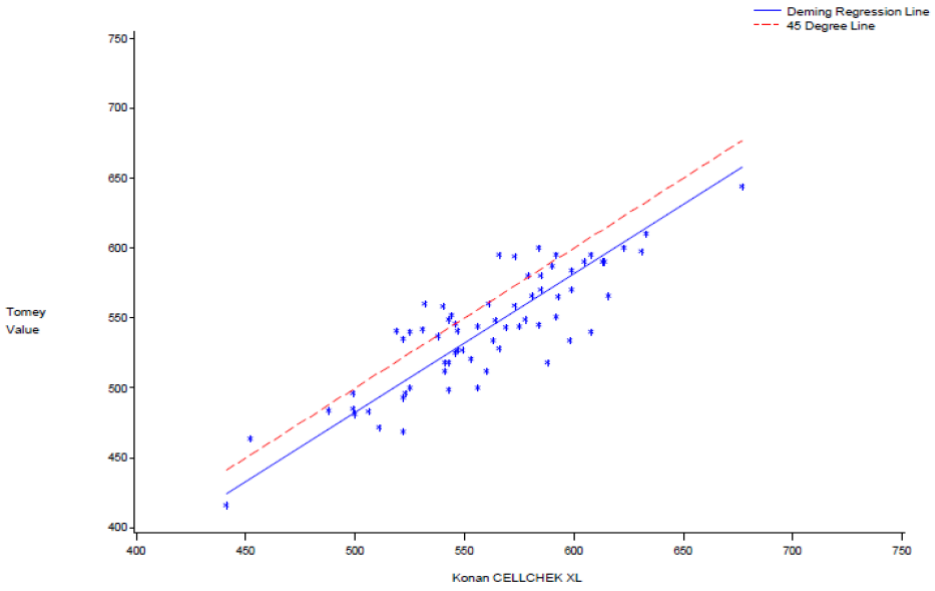


Table 2 Core Method: Precision Analyses − All Subjects − Effectiveness Population

Variable	Tomey EM-4000 N=44	Konan CellChek N=44
Endothelial Cell Density		
Repeatability SD	49.9	65.9
Repeatability SD as a % of the Mean	2.0%	2.5%
Repeatability Limit	139.6	184.4
Repeatability Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.7570	--
Reproducibility SD	54.6	72.7
Reproducibility SD as a % of the Mean	2.2%	2.8%
Reproducibility Limit	152.9	203.4
Reproducibility Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.7514	--

Variable	Tomey EM-4000 N=44	Konan CellChek N=44
Coefficient of Variation of Endothelial Cell Area (CV)		
Repeatability SD	2.0	2.2
Repeatability SD as a % of the Mean	6.1%	7.1%
Repeatability Limit	5.5	6.1
Repeatability Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.8925	---
Reproducibility SD	2.1	2.3
Reproducibility SD as a % of the Mean	6.5%	7.4%
Reproducibility Limit	5.8	6.4
Reproducibility Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.9062	---
% Hexagonality		
Repeatability SD	3.6	4.3
Repeatability SD as a % of the Mean	5.9%	6.8%
Repeatability Limit	10.1	11.9
Repeatability Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.8449	---
Reproducibility SD	4.0	4.3
Reproducibility SD as a % of the Mean	6.5%	6.9%
Reproducibility Limit	11.2	12.0
Reproducibility Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.9271	---
Central Corneal Thickness (CCT)		
Repeatability SD	5.9	17.7
Repeatability SD as a % of the Mean	1.1%	3.1%
Repeatability Limit	16.4	49.7
Repeatability Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.3298	---
Reproducibility SD	7.6	26.6
Reproducibility SD as a % of the Mean	1.4%	4.7%
Reproducibility Limit	21.4	74.4
Reproducibility Ratio (TOMEY EM-4000/ Konan CellChek XL)	0.2874	---

Abbreviations: SD = standard deviation
N represents the total number of subjects in each eye population in the precision and agreement cohort. If any variance component was negative, it was reported as 0. The repeatability limit is 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator+device, operator+device x subject interaction, and residual within subject.

Overall, within eye/subject variability results were reasonably similar for both machines for the parameters measured, as seen in Table 2. The precision of the two devices was assessed with repeatability and reproducibility measures: the first within a given subject and the second

within and among configurations. With regard to overall precision, using the core method, the largest component of variation was the subject to subject variation. The EM-4000 machine was slightly less variable than the CellChek XL machine for all variables: CD, CV, %HEX and CCT.

In summary, for the parameters measured the agreement and precision results of the Tomey EM-4000 core method and the Konan CellChek XL center method were found to be substantially equivalent.

CONCLUSIONS

The Tomey EM-4000 has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicate. The differences between the subject device and the predicate device have been assessed in a human clinical trial which found agreement, accuracy and precision between the two devices. Therefore, the Tomey EM-4000 and the predicate device were determined to be substantially equivalent.