May 11, 2022

Tomey Corporation
% Ryan Bouchard
Consultant
ORA, Inc.
300 Brickstone Square
Andover, Massachusetts 01801

Re: K213265
Trade/Device Name: Tomey Cornea/Anterior Segment OCT CASIA2
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO

Dear Mr. Bouchard:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 27, 2022. Specifically, FDA is updating the 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 240-402-4662, Elvin.Ng@fda.hhs.gov.

Sincerely,

Elvin Y. Ng -S

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

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April 27, 2022

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Trade/Device Name: Tomey Cornea/Anterior Segment OCT CASIA2
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: March 25, 2022
Received: March 28, 2022

Dear Mr. 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. 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 Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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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)*
K213265

Device Name
Tomey Cornea/Anterior Segment OCT CASIA2

Indications for Use *(Describe)*
The Tomey Cornea/Anterior Segment OCT CASIA2 is a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging of ocular structures in the anterior segment. The Tomey Cornea/Anterior Segment OCT CASIA2 is indicated as an aid in the visualization of anterior segment findings.

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.

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"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

This summary of the 510(k) premarket notification for the Tomey Cornea/Anterior Segment OCT CASIA2 is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

Submitter Information:

Owner/Company name, address

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Date Prepared

April 27, 2022

1. Device Information

Trade Name:	Tomey Cornea/Anterior Segment OCT CASIA2
Common Name:	OCT (Optical Coherence Tomography)
Classification Name:	Tomography, optical coherence
Product Code:	OBO
Classification Regulation:	21 CFR 886.1570

2. Predicate Device

The CASIA2 is substantially equivalent to the following legally marketed device:

510(k) Number	Trade name	Product code
K180660	RTVue XR OCT Avanti with AngioVue Software	OBO, HLI

The predicate device is hereinafter called the Avanti.

3. Description of the Device

The Tomey Cornea/Anterior Segment OCT CASIA2 (CASIA2) is a non-contact, high resolution tomographic and biomicroscopic device indicated for in vivo imaging of ocular structures in the anterior segment. The Tomey Cornea/Anterior Segment OCT CASIA2 is indicated as an aid in the visualization of anterior segment findings.

CASIA2 consists of several components: the main unit, AC input power source, a touch panel LCD monitor, an external hard drive (HDD), a mouse and a keyboard.

There are two types of OCT, which are based on different measurement principles: time domain (TD) and Fourier domain (FD). In the TD, the reference mirror is moved mechanically in the direction of depth; in the FD, the depth-wise tissue data is obtained without moving the reference mirror. With the FD, since the reference mirror does not need to be moved mechanically, images can be obtained at a higher speed compared to the TD.

The FD is further classified into spectral-domain OCT [detected in Fourier space using broadband light source and spectroscope (grating) without moving the reference mirror] and swept-source OCT (optical interference performed in the Fourier space by changing the wavelength of the light source at a high speed).

CASIA2 is an anterior segment OCT that obtains images by A-scanning with swept-source OCT. OCT images are created by the intensity of the light (backscattered light) that returns in the same path as that of incident light among the scattered light of each tissue. Thus, it is created with higher intensity in the tissues that generate strong backward scattering.

The various structures which are imaged, and the related scans include the following:

- **Cornea**
  - **AS Global scan**
  - **AS H+V Scan**
  - **AS Single**
- **Lens**
  - **Lens scan**
  - **Lens Raster**
  - **Lens Global scan**
  - **Lens H+V Scan**
  - **Lens Single**
- **Iridocorneal Angle**
  - **Angle HD_N (nasal)**
  - **Angle HD_T (temporal)**
  - **Angle HD_S (superior)**
  - **Angle HD_I (inferior)**

3.1 Performance specification

- Scan speed: 50,000 A scans/second
- Scan Range:
  - Depth: 13mm
  - Radial: 16mm in diameter
  - Transverse: Raster: 12 x 12 mm

4. Indications for Use

The Tomey Cornea/Anterior Segment OCT CASIA2 is a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging of ocular structures in the anterior segment. The Tomey Cornea/Anterior Segment OCT CASIA2 is indicated as an aid in the visualization of anterior segment findings.

5. Statement of substantial equivalence

For its indications, the Tomey Cornea/Anterior Segment OCT CASIA2 has the same intended use as the RTVue XR OCT Avanti for the anterior segment as shown in the comparison table below.

Both the CASIA2 and the Avanti are indicated as an optical coherence tomography system intended for in vivo imaging of anterior ocular structures of the anterior chamber of the eye.

The Tomey OCT CASIA2 does not include the posterior segment indications.

Table 1: Comparison Table of Technological Characteristics

Feature	Tomey CASIA2	Optovue RTVue XR OCT Avanti with AngioVue Software (K180660)
Manufacturer	Tomey	Optovue, Inc.
Classification	886.157	886.157
Product Code	OBO	HLI, OBO
Indications for use	The Tomey Cornea/Anterior Segment OCT CASIA2 is a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging of ocular structures in the anterior segment. The Tomey Cornea/Anterior Segment OCT CASIA2 is indicated as an aid in the visualization of anterior segment findings.	The Avanti is an optical coherence tomography system intended for the in vivo imaging, cross-sectional, and three dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, corneal epithelia, corneal stroma, pachymetry, corneal power, and anterior chamber of the eye. With the integrated normative database, Avanti is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of a known normal subjects. It is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases. The Avanti with the AngioVue software feature is indicated as an aid in the visualization of vascular structures of the retina and choroid in normal subjects, and in subjects with glaucoma and retinal diseases. The AngioAnalytics software feature of AngioVue is indicated for the measurement of vascular density, the foveal avascular zone, the thickness of retinal layers, and nerve fiber layer, and measurement of optic disc parameters in normal subjects, and in subjects with glaucoma and retinal diseases.

Feature	Tomey CASIA2	Optovue RTVue XR OCT Avanti with AngioVue Software (K180660)
Technological Characteristics: OCT		
Imaging	Swept Source OCT	Spectral Domain OCT
Scan Rate	50,000 A-Scan/s	70,000 A-Scan/s
Technological Characteristics: Swept Source Laser		
-Wave Length	1310 nm (LD)	840 nm (SLD)
-Power Output	<6 mW	Unknown
-Continuous/Pulsed	Pulsed	Unknown
-Pulse Durations	12.56μs	Unknown
Field of View	Transverse: Radial scan: 16 mm Raster scan: 12mm x 12mm Scan depth: 13 mm	Corneal image: 12 mm x 8 mm CAM-L: 13 mm
Optical Resolution	Axial: 10μm or less (in tissue) Transverse: 30μm or less (in air)	15μm (in the X and Y directions), 5 μm (in the Z direction)
Exposure Power at Pupil	893 μW	≤750 μW
Technological Characteristics: Internal Fixation Lamp Center		
-Wavelength	605 nm (LED)	Unknown
-Power Output	30mW	Unknown
-Continuous/Pulsed	Continuous	Unknown
Technological Characteristics: Accommodation Target		
Wavelength	605 nm (LED)	Unknown
Power output	30mW	Unknown
Continuous/Pulsed	Continuous	Unknown
Technological Characteristics: External Fixation Lamp		
Wavelength	670 nm (LED)	Unknown
Power output	2.8mW	Unknown
Continuous/Pulsed	Continuous	Unknown
Technological Characteristics: Alignment Lamp		
Wavelength	810 nm (LED)	Unknown
Power output	2.32 ed	Unknown
Continuous/Pulsed	Continuous	Unknown
Technological Characteristics: Front Illumination (red) Lamp		
Wavelength	940 nm (LED)	Unknown
Power output	2.32 ed	Unknown
Continuous/Pulsed	Continuous	Unknown
Technological Characteristics: Front Illumination (green) Lamp		
Wavelength	520 nm (LED)	Unknown
Power output	2.32 ed	Unknown
Continuous/Pulsed	Pulsed	Unknown
Pulse Durations	1/30 sec	Unknown
Technological Characteristics: Others		

Feature	Tomey CASIA2	Optovue RTVue XR OCT Avanti with AngioVue Software (K180660)
Minimum Pupil Diameter	φ 3.0 mm	φ 2.5 mm
Focus Range	- 18 D to +15 D	- 15 D to +12 D
Image Display		
AS Global Scan	AS Global Scan	3D Cornea
AS H+V Scan	AS H+V Scan	Cornea Cross Line
Angle HD	Angle HD_N (nasal) Angle HD_T (temporal) Angle HD_S (superior) Angle HD_I (inferior)	Angle_Nasal Angle_Temporal Angle_Superior Angle_Inferior
AS single	AS single	Cornea line
Lens Scan	Lens Scan	No comparative scan
Lens Raster	Vitreous Raster	No comparative scan
Lens Global Scan	Lens Global Scan	No comparative scan
Lens H+V Scan	Lens H+V Scan	No comparative scan
Lens Single	Lens Single	No comparative scan
Recommended Networking Specifications		
Operating System	Windows® 8.1 or 10 64 bit	Windows 7, 8 and 10; 64-bit OS compatible
Processor Speed	Intel® Core™i5 Processor or higher	3.3 GHz; six-core
Network Bandwidth		1 Gbps or higher
Computer RAM	8GB or more	16 GB or higher
Monitor Resolution		1920 x 1080 at 32-bit color

Substantial Equivalence Discussion for the CASIA2 per the 510(k) Decision-Making Flowchart

1. Is the predicate device legally marketed?

Yes, the predicate device is the Optovue RTVue XR OCT Avanti with AngioVue Software cleared in K180660.

2. Do the devices have the same intended use?

Yes, both devices have the same intended use for the examination of the anterior segment of the eye when comparing the Optovue RTVue XR OCT Avanti with the CAM (cornea anterior module) attachment.

3. Do the devices have the same technological characteristics?

Both the Tomey CASIA2 and the RTVue XR OCT Avanti are OCT devices. The principle of operation is identical in that both devices employ a non-invasive, non-contact low-coherence interferometry technique [specifically, spectral domain optical coherence tomography (SD-OCT)] to generate high-resolution cross-sectional images of internal ocular tissue microstructures by measuring optical reflections from tissue. Both provide cross sectional images of the anterior structures of the eye (i.e., cornea and iris).

There are some identified differences in technological characteristics between the CASIA2 and the RTVue XR OCT Avanti as listed below.

There are minor differences in technological characteristics between the Tomey CASIA2 and the predicate device including scan rate, wavelength, size of field of view, optical resolution, and exposure power at pupil.

There are also minor differences in technological characteristics between the Tomey CASIA2 and the predicate device as related to pupil diameter and focus range.

4. Do the difference technological characteristics of the devices raise different questions of safety and effectiveness?

No, the different technological characteristics do not raise different questions of safety or effectiveness. Both devices use SD-OCT technology to perform *in vivo* viewing, and imaging ocular structures in the anterior segment of the eye.

5.a. Are the methods acceptable?

Yes, the testing methods used are per applicable recognized consensus standards as well as well understood bench and clinical testing protocols.

5.b. Do the data demonstrate substantial equivalence?

Yes, the data demonstrate substantial equivalence. This is discussed further in the Clinical Performance section below.

5.1 Bench Performance Data

Bench testing has been performed to comply with applicable standards to demonstrate that the CASIA2 performs as intended and is substantially equivalent to the predicate device, RTVue XR OCT (K153080) with Cam attachment, with respect to imaging of ocular structures.

Software documentation was provided, and software verification and validation was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and an overall risk assessment regarding security and safety of the device was conducted following ISO 14971:2019-12.

The CASIA 2 device complies with recognized consensus standards regarding electrical safety, optical safety and biocompatibility. The system level testing with software version 4.3 was conducted with passing results.

The CASIA 2 OCT testing conformed to the following standards:

- ISO 15004-1, Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI Z80.36: 2016 American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments
- IEC 60601-1-6 Edition 3.1 2013-10 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance
- ISO 10993-1 Fifth Edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 62304: 2006 Medical devices software – Software life cycle processes

The performance testing demonstrated that the device satisfies the performance requirements specified for its intended use and is equivalent to the relevant performance characteristics of the predicate device.

5.2 Clinical Performance Data

The prospective comparative clinical performance study enrolled 134 subjects (45 normal, 46 cataract, 43 glaucoma). Image Quality was compared to predicate Optovue RTVue Avanti XR OCT, as evaluated by 3 masked graders. Outcomes were pooled for all subjects as well as evaluated separately for normal, cataract, and glaucoma groups, in subjects with a range of cataract severity/types and a range from narrow to open angles.

Images from CASIA2 and Avanti devices for 7 different scan types were assessed for Image Quality based on visibility of anatomic structures (cornea, angle, lens, and iris) and ocular pathology. The image grading procedure was pre-specified in the study protocol and images were assessed by 3 graders masked to subject, disease population, device, and result from other graders. CASIA2 provided better overall image quality in comparison to Avanti in the pooled population for the grader average score as well as in the majority of the individual grader comparisons. The individual populations, normal, cataract, and glaucoma groups, had similar results as the pooled population. For the assessment of the presence of pathology, the CASIA2 images allowed for the observance of pathology more often than Avanti images for all scan types compared. Visibility of angle and lens were observed more often with CASIA2 in comparison to Avanti. Cornea was observed as often with CASIA2 as with Avanti and visibility of iris was observed either as often as or more often with CASIA2 in comparison to Avanti depending on the scan types. The 5 additional scans available for CASIA2 only, with no Avanti comparison, were also assessed for image quality, scores varied from average to good.

5.3 Conclusion

Therefore, based on the same intended use and similar technological characteristics with substantial equivalence to the predicate device confirmed with performance testing, the Tomey CASIA2 is technologically and functionally equivalent to the predicate device, RTVue XR OCT (K153080) for anterior segment imaging. The differences between the proposed device, CASIA2, and the predicate device are not significant and do not raise new issues of safety or effectiveness of the device. The Tomey CASIA2 is as safe and effective as the predicate device, and thus, may be considered substantially equivalent.