



August 29, 2022

Topcon Corporation  
% Maureen O'Connell  
President  
OConnell Regulatory Consultants, Inc.  
44 Oak Street  
Stoneham, Massachusetts 02180

Re: K221111

Trade/Device Name: Non-Mydriatic Retinal Camera NW500  
Regulation Number: 21 CFR 886.1120  
Regulation Name: Ophthalmic Camera  
Regulatory Class: Class II  
Product Code: HKI  
Dated: July 15, 2022  
Received: July 18, 2022

Dear Maureen O'Connell:

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

Sincerely,

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

510(k) Number (if known)

K221111

Device Name

NON-MYDRIATIC RETINAL CAMERA NW500

Indications for Use (Describe)

The Non-Mydriatic Retinal Camera NW500 intended for use in capturing images of the retina and presenting the data to the eye care professional, without the use of a mydriatic.

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  
TOPCON CORPORATION  
NON-MYDRIATIC RETINAL CAMERA NW500**

**GENERAL INFORMATION**

**Submitter's information:**

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

**Contact person:**

Maureen O'Connell  
O'Connell Regulatory Consultants, Inc.  
44 Oak Street  
Stoneham, MA 02180  
Phone:978-207-1245

**Date Prepared:**

August 29, 2022

**DEVICE INFORMATION**

**SUBJECT DEVICE(S):**

**Name of Device:** NON-MYDRIATIC RETINAL CAMERA NW500  
**Classification Name:** Class II  
21 CFR 886.1120 (Ophthalmic camera)  
**Product Code:** HKI

**PREDICATE DEVICE:**

**Company** Topcon Corporation  
**Device** TRC-NW400 Non-Mydriatic Retinal Camera  
**510(k) No.** K141481

### Brief Device Description

The Non-Mydriatic Retinal Camera NW500 is a non-mydriatic and slit-scanning ophthalmic camera intended to capture, display and store images of the retina and the surrounding adnexa (the fundus oculi) to aid in the diagnosis. It has automatic functions such as auto-alignment, auto-focus, auto-shoot and auto-small pupil functions which can be switched ON/OFF or automatic/manual operation. Eyes with pupil diameters of 2.0mm or more are photographable with NW500.

### Intended Use / Indications for Use

The Non-Mydriatic Retinal Camera NW500 intended for use in capturing images of the retina and presenting the data to the eye care professional, without the use of a mydriatic.

### Performance Data

It has been verified that NW500 functions as intended by tests or evaluations based on the following FDA-recognized, voluntary consensus standards, and the in-house test specification. The results of the testing support substantial equivalence by demonstrating that the device performs as intended and complies with the same standards as the predicate device.

| <b>FDA-recognized, voluntary consensus standards</b>                              |   |
|---|---|
| ISO 15004-1:2006  | Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments  |
| ISO 10940:2009  | Ophthalmic instruments – Fundus cameras   |
| ANSI Z80.36-2016  | American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments (FDA-recognized consensus standard)   |
| ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance  |
| IEC 60601-1-2:2014  | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances-Requirements and tests |
| IEC 60601-1-6: 2013   | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability   |
| IEC 62366-1:2015  | Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]  |
| ISO 10993-1:2018  | Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process  |
| ISO 10993-5:2009  | Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity  |
| ISO 10993-10:2010   | Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization   |
| <b>In-house test specification</b>  |   |
| Bench Testing   | In-house test specification   |

Software of NW500 was concluded to be a Moderate Level of Concern. Software verification and validation testing were performed, and documentation is provided as recommended by the FDA's guidance document, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (issued on May 11, 2005).

**Clinical Performance Data**

This section is not applicable because clinical data was not provided for this 510(k) submission.

**Substantial Equivalence**

The subject device, NW500 is substantially equivalent to the predicate device because the intended use/indications for use, operation principle and technological characteristics of NW500 is substantially equivalent to those of the predicate device as shown in **Table 1**.

Also, it has been confirmed by bench tests that slight differences of NW500 compared to the predicate device do not affect the safety and effectiveness as an ophthalmic camera.

**Table 1: Substantial Equivalence**

| <b>Model Number</b>                                     | <b>NW500<br/>(Subject device)</b>  | <b>TRC-NW400<br/>(Predicate device)</b>  | <b>Substantial Equivalence<br/>Discussion</b>  |
|---|--|--|--|
| <b>Trade Name</b>                                       | NON-MYDRIATIC RETINAL CAMERA NW500   | TRC-NW400<br>NON-MYDRIATIC RETINA  | N/A  |
| <b>510(k)<br/>submitter/holder</b>                      | TOPCON Corporation   | TOPCON Corporation   | Same   |
| <b>510(k) Number</b>                                    | NA   | K141481  | N/A  |
| <b>Product code</b>                                     | HKI  | HKI  | Same   |
| <b>Regulation No.</b>                                   | 886.1120   | 886.1120   | Same   |
| <b>Product class</b>                                    | II   | II   | Same   |
| <b>Indications for Use</b>                              | The Non-Mydriatic Retinal Camera NW500 intended for use in capturing images of the retina and presenting the data to the eye care professional, without the use of a mydriatic.  | The TRC-NW400 intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, without use of a mydriatic.   | Substantially equivalent   |
| <b>Technological Characteristics:<br/>Device Design</b> | <p>NW500 is a non-mydriatic and slit-scanning ophthalmic camera intended to capture, display and store images of the retina and the surrounding adnexa (the fundus oculi) to aid in the diagnosis. It has automatic functions such as auto-alignment, auto-focus, auto-shoot and auto-small pupil functions which can be switched ON/OFF or automatic/manual operation. Eyes with pupil diameters of 2.0mm or more are photographable with NW500.</p> <p>The digital cameras incorporated in the main unit capture images of the retina and the surrounding adnexa (the fundus oculi), and the control panel (LCD touch panel) displays the captured images (live or static images) and their associated information (such as patient/test/photography information). The captured images (static images) can also be displayed on a commercially available monitor of a personal computer (hereafter called "PC") by using the capturing software, Ez Capture for NW500 which is one of the accessories of NW500. The captured images (static images) and their associated information (such as patient/test/photography</p> | <p>The Topcon TRC-NW400 is a fundus camera designed to observe, photograph and record the fundus oculi of a patient's eye with or without the use of a mydriatic. The TRC-NW400 does not come into contact with the patient's eye and provides the fundus oculi image information as an electronic image for later analysis. The TRC-NW400 houses a color LCD monitor used for observation and display of a photographed image and a digital photography unit used for recording images. A photographed image may be recorded on a personal computer (hereinafter referred to as a PC), or on a commercially available storage device (such as a flash memory, a hard disk or a card reader/writer) connected to the TRC-NW400. A photographed image may also be printed on a commercially available digital printer connected to the TRC-NW400 or PC. Patient information may be input on the control panel of the main unit or by using a commercially available data input device (for example: a bar code reader or a magnetic card reader) or PC.</p> | <p>Substantially equivalent</p> <p>The subject device (NW500) and the predicate device (TRC-NW400) have equivalent technological characteristics as ophthalmic cameras to capture, display and store images of the fundus oculi, although they have slight differences in having or not the slit-scanning movement and in the photographable pupil diameters, both of which do not affect the intended use nor the target population. Also, the performance and the safety of the subject device (NW500) have been verified by tests as described in "Performance Data" above.</p> |

| Model Number                           | NW500<br>(Subject device)  | TRC-NW400<br>(Predicate device) | Substantial Equivalence<br>Discussion   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
|--|--|---------------------------------|---|--------------------------|------------------------------|---------------------------|---|-----------------------|-----|--|---|--------------------|--------|----------------------------------|---|--|------|----------------------|--------------------------|------------------------------|---------------------------|---|-----------------------|---------|--|---|--------------------|--------|----------------------------------|---|---------------------------------|
|  | <p>information) can be exported to and stored in commercially available USB flash drives, PCs, servers (such as a DICOM server) and shared network folders as electric data, and they can be printed out from commercially available printers.</p>   |                                 | <p>Therefore, those slight differences do not affect safety and effectiveness as an ophthalmic camera, and the subject device (NW500) is substantially equivalent to the legally marketed predicate device (TRC-NW400).</p> |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| <p><b>Device Specifications</b></p>    | <table border="1"> <thead> <tr> <th data-bbox="464 540 596 573">Item</th> <th data-bbox="596 540 995 573">Device Specification</th> </tr> </thead> <tbody> <tr> <td data-bbox="464 573 596 670">Types of image-capturing</td> <td data-bbox="596 573 995 670">Color<br/>Infrared light (IR)</td> </tr> <tr> <td data-bbox="464 670 596 833">Resolving power on fundus</td> <td data-bbox="596 670 995 833">Color image-capturing                             <ul style="list-style-type: none"> <li>● Center: 60 lp/mm or more</li> <li>● Middle (r/2): 40 lp/mm or more</li> <li>● Periphery (r): 25 lp/mm or more</li> </ul> </td> </tr> <tr> <td data-bbox="464 833 596 930">Angular Field of View</td> <td data-bbox="596 833 995 930">50°</td> </tr> <tr> <td data-bbox="464 930 596 1157">Measuring range for the dioptric power</td> <td data-bbox="596 930 995 1157">-33 D to +40 D<br/>When used without diopter correction lens: -13D to +12D<br/>When used with the minus diopter correction lens: -33D to -12 D<br/>When used with the plus diopter correction lens: +11D to +40D</td> </tr> <tr> <td data-bbox="464 1157 596 1222">Operating distance</td> <td data-bbox="596 1157 995 1222">35.5mm</td> </tr> <tr> <td data-bbox="464 1222 596 1352">Photographable diameter of pupil</td> <td data-bbox="596 1222 995 1352">Normal: φ2.5mm or more<br/>Small pupil: φ2.0mm or more</td> </tr> </tbody> </table> | Item                            | Device Specification  | Types of image-capturing | Color<br>Infrared light (IR) | Resolving power on fundus | Color image-capturing <ul style="list-style-type: none"> <li>● Center: 60 lp/mm or more</li> <li>● Middle (r/2): 40 lp/mm or more</li> <li>● Periphery (r): 25 lp/mm or more</li> </ul> | Angular Field of View | 50° | Measuring range for the dioptric power | -33 D to +40 D<br>When used without diopter correction lens: -13D to +12D<br>When used with the minus diopter correction lens: -33D to -12 D<br>When used with the plus diopter correction lens: +11D to +40D | Operating distance | 35.5mm | Photographable diameter of pupil | Normal: φ2.5mm or more<br>Small pupil: φ2.0mm or more | <table border="1"> <thead> <tr> <th data-bbox="1056 540 1188 573">Item</th> <th data-bbox="1188 540 1577 573">Device Specification</th> </tr> </thead> <tbody> <tr> <td data-bbox="1056 573 1188 670">Types of image-capturing</td> <td data-bbox="1188 573 1577 670">Color<br/>Infrared light (IR)</td> </tr> <tr> <td data-bbox="1056 670 1188 898">Resolving power on fundus</td> <td data-bbox="1188 670 1577 898">Color image-capturing                             <ul style="list-style-type: none"> <li>● Center: 60 lp/mm or more</li> <li>● Middle (r/2): 40 lp/mm or more</li> <li>● Periphery (r): 25 lp/mm or more</li> </ul> </td> </tr> <tr> <td data-bbox="1056 898 1188 995">Angular Field of View</td> <td data-bbox="1188 898 1577 995">45°/30°</td> </tr> <tr> <td data-bbox="1056 995 1188 1222">Measuring range for the dioptric power</td> <td data-bbox="1188 995 1577 1222">-33 D to +40 D<br/>When used without diopter correction lens: -13D to +12D<br/>When used with the minus diopter correction lens: -33D to -12 D<br/>When used with the plus diopter correction lens: +11D to +40D</td> </tr> <tr> <td data-bbox="1056 1222 1188 1287">Operating distance</td> <td data-bbox="1188 1222 1577 1287">34.8mm</td> </tr> <tr> <td data-bbox="1056 1287 1188 1417">Photographable diameter of pupil</td> <td data-bbox="1188 1287 1577 1417">Normal: φ4.0mm or more<br/>Small pupil: φ3.3mm or more</td> </tr> </tbody> </table> | Item | Device Specification | Types of image-capturing | Color<br>Infrared light (IR) | Resolving power on fundus | Color image-capturing <ul style="list-style-type: none"> <li>● Center: 60 lp/mm or more</li> <li>● Middle (r/2): 40 lp/mm or more</li> <li>● Periphery (r): 25 lp/mm or more</li> </ul> | Angular Field of View | 45°/30° | Measuring range for the dioptric power | -33 D to +40 D<br>When used without diopter correction lens: -13D to +12D<br>When used with the minus diopter correction lens: -33D to -12 D<br>When used with the plus diopter correction lens: +11D to +40D | Operating distance | 34.8mm | Photographable diameter of pupil | Normal: φ4.0mm or more<br>Small pupil: φ3.3mm or more | <p>Substantially equivalent</p> |
| Item                                   | Device Specification   |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Types of image-capturing               | Color<br>Infrared light (IR)   |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Resolving power on fundus              | Color image-capturing <ul style="list-style-type: none"> <li>● Center: 60 lp/mm or more</li> <li>● Middle (r/2): 40 lp/mm or more</li> <li>● Periphery (r): 25 lp/mm or more</li> </ul>  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Angular Field of View                  | 50°  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Measuring range for the dioptric power | -33 D to +40 D<br>When used without diopter correction lens: -13D to +12D<br>When used with the minus diopter correction lens: -33D to -12 D<br>When used with the plus diopter correction lens: +11D to +40D  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Operating distance                     | 35.5mm   |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Photographable diameter of pupil       | Normal: φ2.5mm or more<br>Small pupil: φ2.0mm or more  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Item                                   | Device Specification   |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Types of image-capturing               | Color<br>Infrared light (IR)   |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Resolving power on fundus              | Color image-capturing <ul style="list-style-type: none"> <li>● Center: 60 lp/mm or more</li> <li>● Middle (r/2): 40 lp/mm or more</li> <li>● Periphery (r): 25 lp/mm or more</li> </ul>  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Angular Field of View                  | 45°/30°  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Measuring range for the dioptric power | -33 D to +40 D<br>When used without diopter correction lens: -13D to +12D<br>When used with the minus diopter correction lens: -33D to -12 D<br>When used with the plus diopter correction lens: +11D to +40D  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Operating distance                     | 34.8mm   |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |
| Photographable diameter of pupil       | Normal: φ4.0mm or more<br>Small pupil: φ3.3mm or more  |                                 |   |                          |                              |                           |   |                       |     |  |   |                    |        |                                  |   |  |      |                      |                          |                              |                           |   |                       |         |  |   |                    |        |                                  |   |                                 |



| Model Number | NW500<br>(Subject device) |  | TRC-NW400<br>(Predicate device) |   | Substantial Equivalence<br>Discussion |
|--------------|---------------------------|--|---------------------------------|---|---------------------------------------|
|              | Fixation target           | Internal fixation target<br>External fixation target           | Fixation target                 | Internal fixation target<br>External fixation target<br>Peripheral fixation target                            |                                       |
|              | Auxiliary functions       | Auto-alignment<br>Auto-focus<br>Auto-shoot<br>Auto-small pupil | Auxiliary functions             | Auto-alignment<br>Auto-focus<br>Auto-shoot<br>Auto small pupil diaphragm function<br>Blink detection function |                                       |