April 1, 2019

Nidek Co., Ltd
% Enrico Bisson
Manager, Regualatory Affairs Department
Nidek Technologies Srl
Via dell'Artigianato, 6/A
Albignasego, 35020 It

Re: K190198
Trade/Device Name: Microperimeter MP-3, Microperimeter MP-3 Type S
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI, HPT
Dated: January 29, 2019
Received: February 4, 2019

Dear Enrico Bisson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 yours,

Alexander Beylin -S 2019.04.01 12:21:16 -04'00'

for Malvina B. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190198

Device Name
Microperimeter MP-3, Microperimeter MP-3 Type S

Indications for Use *(Describe)*
The MICROPERIMETER MP-3 and MICROPERIMETER MP-3 Type S are indicated for use as:
Color retinography
Fixation examiner
Fundus-related microperimetry
Visual rehabilitation

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

Preparation Date: 3/20/2019

Contact Details — 21 CFR 807.92(a)(1)

Applicant Name	NIDEK CO., LTD.
Applicant Address	34-14 Maehama, Hiroishi-cho Gamagori, AICHI, 443-0038, JA
Applicant Telephone Number	011-815-33678901
Applicant Contact	Mr. Mizuno Yoneji
Applicant Contact Email	Yoneji_Mizuno@nidek.co.jp
Correspondent Name	Nidek Technologies srl
Correspondent Address	Via dell'Artigianato, 6/A, Albignasego, Padova, 35020, IT
Correspondent Telephone Number	003-932-86439091
Correspondent Contact	Mr. Enrico Bisson
Correspondent Contact Email	enricobisson@nidektechncologies.it

Device Name — 21 CFR 807.92(a)(2)

Device Trade Name	Microperimeter MP-3
Common Name	OPTHALMIC CAMERA.
Classification Name	CAMERA, OPHTHALMIC, AC-POWERED; PERIMETER, AUTOMATIC, AC-POWERED
Regulation Number	886.1120
Product Code	HKI; HPT

Legally Marketed Predicate Devices — 21 CFR 807.92(a)(3)

Predicate (510(k)) #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K061768	MP-1 MICRO PERIMETER	HKI
K152729	Microperimeter MP-3	HKI

Device Description Summary — 21 CFR 807.92(a)(4)

The modified NIDEK Microperimeter MP-3 and MP-3 type S measure the visual sensitivity of a specified area on the fundus and captures color fundus images. The fundus image overlaid with the retinal sensitivity mapping is displayed on the screen for fundus-image-correlated evaluation. With reference to the Microperimeter MP-3, cleared with K152729, a rehabilitation function and the capability to performs exams in scotopic environments (only MP-3 type S) have been added.

Visual sensitivity mapping function
Visual sensitivity mapping can be displayed using static perimetry principle.
Stimuli and a fixation target are displayed by the built-in LCD projector. While focusing on the fixation target, the patient presses the response button to indicate that they saw a stimulus projected at the location and light intensity specified by the internal measurement program or the operator. The patient's response signals are computed by the device and measurement results are displayed on the LCD.

Fixation function
The MicroperimeterMP-3 can measure fixation and determine the preferred retinal locus, simply by having the patient fixate on a target. Any change in fixation can be compared pre- and post-treatment because the patient's eye is constantly tracked during microperimetry.

Fundus photography function
Auto alignment is performed while observing on the LCD, the front of the patient's eye illuminated by the eye front illumination LED (infrared light). After the alignment is roughly complete, the mode automatically changes to the fundus observation mode.
The fundus of the patient's eye is illuminated by the fundus illumination LED (infrared light). After alignment and focusing are automatically performed on the fundus, white light from the xenon flash lamp is emitted on the fundus. The light reflected from the fundus is captured by the built-in color CCD camera for fundus image capture.

Visual rehabilitation

510(k) Summary

Preparation Date: 3/20/2019

Visual rehabilitation is a collective name of Fundus-related microperimetry, Feedback exam, and Fixation exam. They are used to support the fixation training for patient.
Feedback exam: similar function with the Fixation exam. The screens for the patient are the same as those in Fixation exam, Feedback exam, and Fixation exam, and differ only in the following characteristics: in the Feedback exam, a sound is heard and the appearance of the fixation target changes when the patient's vision is fixed on any position inside the circle specified by the operator (TRL Trained[target] Retinal Locus, which the patient cannot see).

Intended Use/Indications for Use — 21 CFR 807.92(a)(5)

The MICROPERIMETER MP-3 and MICROPERIMETER MP-3 Type S are indicated for use as:
Color retinography
Fixation examiner
Fundus-related microperimetry
Visual rehabilitation

Indications for Use Comparison — 21 CFR 807.92(a)(5)

The indications for use are identical.

Technological Comparison — 21 CFR 807.92(a)(6)

The Microperimeter MP-3 and MP-3 Type S are substantially equivalent to the predicate device with regard to design, function, technological characteristics, intended use and performance characteristics.
The differences between the proposed and predicate device and justifications as to why these differences do not raise safety or efficacy concerns are as follows.
Differences in Color retinography
The subject device may perform alignment and focusing automatically, while the predicate device performs the same operation only manually.

Differences in Fixation examiner
The subject device may perform alignment and focusing automatically, while the predicate device performs the same operation only manually. The exam is performed in the same way, but the subject device has improved the result display.

Differences in Fundus-related microperimetry
The subject device may perform alignment and focusing automatically, while the predicate device performs the same operation only manually.

The background luminance can be set at 31.4 asb or 4 asb or 0.003 asb (Type S), while the predicate device allowed only 4 asb.
The minimum stimulus luminance is 4.4 asb (4 asb - white on white - 34 dB mode) and 35.4 asb (31.4 asb white on white 34 dB mode) and for Type S 0.0042 asb (0.003 asb - white on white - 24 dB mode), while the predicate device allows only 8 asb.
The maximum stimulus luminance is 10,031.4 asb, while the predicate device allows only 404 asb.
These larger ranges don't raise any safety issue. Compliances with both the light hazard recognized standards ISO 15004-1 and ANSI Z80.36, and voluntary ISO 12866 standards are documented.
Differences in Visual Rehabilitation
In the predicate device the bio-feedback audible signal consists of an intermitting sound, with frequency increasing the closer the new PRL is to (center of) the central target until a continuous sound is heard. The subject device allows both continuous sound and music when the exam is successfully completed.
The subject device allows user to change the position of the Stimulation Pattern, while the predicate doesn't allow.
The design modifications outlined in this Traditional 510(k) premarket notification do not (1) affect the intended use or the indication for use or (2) alter the fundamental scientific technology of the device. The proposed Microperimeter MP-3 and MP-3 Type S share the equivalent indications for use, the same technological characteristics and the same principle of operation as the predicate devices. Therefore, based on the similarities between the devices, the proposed Microperimeter MP-3 is substantially equivalent to MP-1MICRO PERIMETER (K061768) .
Testing in Support of Substantial Equivalence Determination
We have verified and validated that the Microperimeter MP-3 and MP-3 Type S meet its functional specifications and performance requirements, and complies with applicable international standards (IEC 60601-1, IEC 60601-1-2, ISO 15004-1, ANSI Z80.36, ISO 12866, ISO 10940).
As mentioned, all necessary bench testing was conducted on the modifications, the addition of the proposed Microperimeter MP-3 and MP-3 Type S, to support a determination of substantial equivalence to the predicate device.
Summary of Safety and Effectiveness
All the necessary safety tests were performed and documented. The results demonstrate that the subject device complies with applicable international standards (IEC 60601-1, IEC 60601-1-2, ISO 15004-1, ANSI Z80.36, ISO 12866, ISO 10940) and it is safe as the predicate device.

510(k) Summary

Preparation Date: 3/20/2019

All the necessary performance tests in support of substantial equivalence determination were conducted. The tests demonstrate that the subject device is effective and performs as well as the predicate device. The minor differences between the devices do not raise any new issues of safety or efficacy.
Thus the proposed Microperimeter MP-3 and MP-3 Type S are substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Summary:
We have verified and validated that the Microperimeter MP-3 meets its functional specifications and performance requirements, and complies with applicable international standards ISO 15004-1, ANSI Z80.36, ISO 10940, ISO 12866, IEC 62304 and IEC 62366-1. Software verification and validation were performed according to the internal Software Design and Development Procedure in compliance with IEC 62304. The software of this device was considered as a "Moderate" level of concern based on the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on: May 11, 2005.

Clinical Summary:
Not Applicable

Conclusions:
All the necessary safety tests were performed and documented. The results demonstrate that the subject device complies with applicable international standards ISO 15004-1, ANSI Z80.36, ISO 10940, ISO 12866, IEC 62304 and IEC 62366-1 and it is safe as the predicate device. All the necessary performance tests in support of substantial equivalence determination were conducted. The tests demonstrate that the subject device is effective and performs as well as the predicate device. The minor differences between the devices do not raise any new issues of safety or efficacy.