DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 25, 2016

Hamamatsu Photonics K.K.
% Ms. Allyson Mullen
Hyman, Phelps & Mcnamara
700 Thirteenth Street, Northwest, Suite 1200
Washington, District of Columbia 20005

Re: K162117
Trade/Device Name: Niro-200NX DP
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD, DQA
Dated: July 29, 2016
Received: July 29, 2016

Dear Ms. Mullen:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162117

Device Name
NIRO-200NX DP

Indications for Use *(Describe)*
The NIRO-200NX DP is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes in any individual. The clinical value of trend data has not been demonstrated in disease states. The NIRO-200NX DP should not be used as the sole basis for diagnosis or therapy.

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
K162117 – NIRO-200NX DP

Submitter Name:	Hamamatsu Photonics K.K.
Submitter Address:	812 Joko-cho, Higashi-ku, Hamamatsu City, 431-3196, JAPAN
Contact Person:	Susumu Suzuki
Phone Number:	81-53-431-0124
Fax Number:	81-53- 431-0148
Date Prepared:	October 24, 2016
Device Trade Name:	NIRO-200NX DP
Device Common Name:	Oximeter
Product Code:	MUD
Subsequent Product Code:	DQA
Classification:	Class II per 21 C.F.R. § 870.2700
Predicate Device:	Hamamatsu NIRO-200NX (K143219)

Device Description: The NIRO-200NX is a piece of equipment that uses near infrared light for non-invasive measurement of hemoglobin oxygen saturation and relative levels of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes. Patient probes are applied to the skin over the tissue of interest. The probes have a light source and 2 photodiodes, one closer to the light source and one further away from the light source. The 2 photodiodes detect the light transmitted through the patient's tissue. The detected light is analyzed with the known light absorption characteristics of oxyhemoglobin and deoxyhemoglobin. The amount of light detected by the photodiode closer to the light source is subtracted from the light detected by the farther photodiode. The result is

then used to calculate the hemoglobin oxygen saturation. Also, by measuring the changes in light detected from one of the photodiodes, the relative levels of oxygenated hemoglobin and deoxygenated hemoglobin are calculated.

The predicate NIRO-200NX (K143219) utilized reusable patient probes. The purpose of this premarket notification is to obtain clearance for use of disposable probes and compatible connectors with the cleared display unit. Use of the disposable probes and compatible connectors with the cleared display unit is referred to as the NIRO-200NX DP.

Intended Use: The NIRO-200NX DP is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes in any individual. The clinical value of trend data has not been demonstrated in disease states. The NIRO-200NX DP should not be used as the sole basis for diagnosis or therapy.

Performance Data: The following electrical and performance data have been generated using the NIRO-200NX DP and are described in this 510(k) submission. All tests demonstrate that the device functions as intended.

1. Electrical Safety was established by testing in accordance with IEC 60601-1 Edition 3.0, Medical Electrical Equipment – Part 1: General requirements for Safety (2005)

2. Electromagnetic Compatibility was established by testing in accordance with IEC 60601-1-2 3rd Edition, Medical Electrical Equipment – Part 1-2: Electromagnetic Compatibility – Requirements and Tests (2008).

3. Laser Safety was established by testing in accordance with IEC 60825-1 Ed. 2.0 (2007). The light source in the NIRO-200NX DP is a Class 1 Light Emitting Diode (LED) Product.

4. Report on the Tissue Phantom Measurements with NIRO-200NX Reusable and Disposable Probes. Hamamatsu

performed a phantom study to compare performance of the proposed and predicate device side by side in a simulated model. The results of the study demonstrate that performance of the NIRO-200NX DP is substantially equivalent to the performance of the NIRO-200NX (K143219).

5. The NIRO-200NX DP has been sold and used clinically for more than two years in Japan and Europe without any reported adverse events.

6. Hamamatsu followed the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005," to classify the NIRO-200NX software as a "moderate level of concern." The software was verified and validated, and the software verification and validation documents were prepared and presented in accordance with FDA's guidance document.

Substantial Equivalence:

The predicate device is the Hamamatsu NIRO-200NX (K143219).

The NIRO-200NX DP has the same intended use, indications for use, principle of operation, and measurement method as the predicate device. The NIRO-200NX DP and the predicate device have similar technological characteristics. The only difference is the inclusion of a disposable probe option, which includes a compatible adapter and AMPs for connection of the disposable probes to the NIRO-200NX display unit. This minor difference does not raise different questions of safety or efficacy, as confirmed by Hamamatsu's testing and validation activities described in this submission, including EMC, electrical safety, and laser safety testing in accordance with IEC 60601-1-2 (2008), IEC 60601-1 (2005), and IEC 60825-1 Ed. 2.0 (2007). Hamamatsu followed the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005," to classify the NIRO-200NX software as a "moderate level of concern." The software was verified and validated, and the software verification and validation documents were prepared and presented in accordance with FDA's guidance document.

Further, NIRO-200NX DP is at least as safe and effective as the predicate devices as demonstrated by the results of a phantom study. Hamamatsu performed a phantom study to compare performance of the proposed and predicate devices side by side in a simulated model. The results of the study demonstrated that performance of the NIRO-200NX DP is substantially equivalent to the performance of NIRO-200NX at measuring regional hemoglobin oxygen saturation and relative levels of oxygenated hemoglobin and deoxygenated hemoglobin.

The data presented demonstrate that the NIRO-200NX DP is at least as safe and effective as the predicate NIRO-200NX. Therefore, the NIRO-200NX DP is substantially equivalent to the predicate device. The Substantial Equivalence comparison chart is found below in Table 1.

Table 1: Comparison to Predicate

	Subject Device: **NIRO-200NX DP**	**Predicate Device:** **NIRO-200NX (K143219)**
Intended Use	Oximeter (MUD, DQA)	Oximeter (MUD, DQA)
Indications for Use	The NIRO-200NX DP is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes in any individual. The clinical value of trend data has not been demonstrated in disease states. The NIRO-200NX DP should not be used as the sole basis for diagnosis or therapy.	The NIRO-200NX is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation and relative level of oxygenated hemoglobin and deoxygenated hemoglobin of blood in brain or in other tissue beneath the probes in any individual. The clinical value of trend data has not been demonstrated in disease states. The NIRO-200NX should not be used as the sole basis for diagnosis or therapy.

	Subject Device: **NIRO-200NX DP**	**Predicate Device:** **NIRO-200NX (K143219)**
Principle of Operation	The NIRO-200NX DP is intended for use in a hospital setting by healthcare professionals. To use the NIRO-200NX DP, the probes are placed on any healthy tissue of the patient. The probes can remain on the patient for up to 12 hours, and measurement data can be continuously collected (at a maximum sampling rate of 20Hz (0.05s)) over that time period. The data recorded from the probe is calculated as discussed below and reported on the LCD on the DU for monitoring by the physician.	The NIRO-200NX is intended for use in a hospital setting by healthcare professionals. To use the NIRO-200NX, the probes are placed on any healthy tissue of the patient. The probes can remain on the patient for up to 12 hours, and measurement data can be continuously collected (at a maximum sampling rate of 20Hz (0.05s)) over that time period. The data recorded from the probe is calculated as discussed below and reported on the LCD on the DU for monitoring by the physician.
Technological Characteristics		
Display Unit (DU)	Liquid crystal display (LCD) and instrument control panel	Liquid crystal display (LCD) and instrument control panel
Probes	Disposable	Reusable
Adaptor	Disposable Probe Adaptor (DPA)	Pulse 2ch Adaptor (P2A)
AMP Unit	DPA AMP Unit	AMP Unit

	Subject Device: **NIRO-200NX DP**	**Predicate Device:** **NIRO-200NX (K143219)**
Light Source Device Wavelength Safety Class	LED (Light Emitting Diode) 3 wavelengths Class I	LED (Light Emitting Diode) 3 wavelengths Class I
Light Detector	Photodiode	Photodiode
Measurement Method	2 Point Detection Method for Hemoglobin Oxygen Saturation (TOI) and Relative value of the total hemoglobin (nTHI) 1 Point Detection Method for Relative Levels of Hemoglobins	2 Point Detection Method for Hemoglobin Oxygen Saturation (TOI) and Relative value of the total hemoglobin (nTHI) 1 Point Detection Method for Relative Levels of Hemoglobins
Patient Contact	Non-Invasive	Non-Invasive
EMC and Electrical Safety	Passed applicable safety testing	Passed applicable safety testing

Conclusion: Based on the indications for use, performance testing, and technological characteristics, the NIRO-200NX DP has been shown to be as safe and effective for its stated intended use as the NIRO-200NX (K143219).