**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Nonin Medical Inc.
Laura Lind
Sr. Regulatory Affairs Specialist
13700 1st Avenue North
Plymouth, Minnesota 55441

Re: K151305
Trade/Device Name: SenSmart Model 8203CA Regional Oximetry Sensor, SenSmart Model 8204CA Regional Oximetry Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: July 30, 2015
Received: July 31, 2015

Dear Laura Lind:

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.

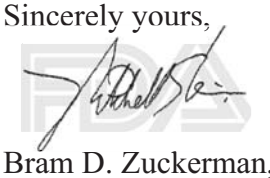
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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 yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K151305 - Page 1 of 1

Device Name
SenSmart™ Model 8203CA Regional Oximetry Sensor
SenSmart™ Model 8204CA Regional Oximetry Sensor

Indications for Use *(Describe)*

Model 8203CA

The Model 8203CA single-patient use, non-sterile, disposable sensor is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor of adult or pediatric patients weighing greater than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8203CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments.

Model 8204CA

The Model 8204CA single-patient use, non-sterile, disposable sensor is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8204CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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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."*

## 5. "510(k) Summary" as required by section 807.92(c)

| | |
|---|---|
| **Submitter:** | Nonin Medical, Inc. |
| | 13700 1st Ave. North<br>Plymouth, MN 55441-5443 |
| **Phone:** | 763-553-9968 |
| **Fax:** | 763-553-7807 |
| **Contact Person:** | Laura Lind<br>Senior Regulatory Affairs Specialist |
| **Date Prepared:** | May 15, 2015 |
| **Trade Names:** | SenSmart™ Model 8203CA Regional Oximetry Sensor<br>SenSmart™ Model 8204CA Regional Oximetry Sensor |
| **Common Name:** | Regional oximetry sensor |
| **Classification Name:** | Oximeter, Tissue Saturation |
| **Regulation Number:** | Class II, 21 CFR 870.2700 (Oximeter) |
| **Product Code, Panel:** | MUD, Cardiovascular |
| **Predicate Device(s):** | The Nonin SenSmart Model 8203CA and Model 8204CA Regional Oximetry Sensors are predicated on the Nonin SenSmart Model 8003CA and Model 8004CA Regional Oximetry Sensors cleared under K102715 (December 17, 2010.) |
| **Device Description:** | The SenSmart Model 8203CA Regional Oximetry Sensor (Model 8203CA) and SenSmart Model 8204CA Regional Oximetry Sensor (Model 8204CA) are single-patient use, non-sterile disposable regional (tissue saturation) sensors intended for use with the Nonin Medical Model X-100 SenSmart Regional Oximetry System (Model X-100). The proposed devices are also compatible with the Nonin Model 7600 Regional Oximeter (Model 7600). |
| **Intended Use:** | **Model 8203CA**<br>The Model 8203CA single-patient use, non-sterile, disposable sensor is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor of adult or pediatric patients weighing greater than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8203CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments. |



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**Model 8204CA**

The Model 8204CA single-patient use, non-sterile, disposable sensor is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8204CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments.

**Testing:**

The Nonin Model 8203CA and Model 8204CA sensors are supported by safety, electromagnetic compatibility, device performance, and clinical testing to ensure appropriate functionality and to demonstrate substantial equivalence to the predicate devices. The devices were tested with the Model X-100 system.

**Functional and Safety Testing:**

The results of the testing demonstrate equivalency with the predicate devices and compliance to recognized standards. Table 1 summarizes test results for the proposed devices, which met the relevant requirements of the applicable recognized standards.

**Table 1**

| Test | Reference | Result |
|---|---|---|
| Electrical Safety | IEC 60601-1 | Pass |
| Temperature and Humidity | IEC 60601-1<br>EN 1789 | Pass |
| Atmospheric Pressure (Altitude) | IEC 60601-1 | Pass |
| Electromagnetic Immunity and Emissions | IEC 60601-1-2 | Pass |
| Performance | ISO 80601-2-61<br>IEC 60601-1<br>IEC 60601-1-6; IEC 60601-1-12<br>IEC 62304<br>ANSI/AAMI EC13<br>ISO 14155-1; ISO 14155-2 | Pass |
| Ingress Protection | ISO 80601-2-61 | Pass |
| Diaphoretic related ingress | Internal performance characterization | Pass |
| Mechanical Durability | IEC 60601-1<br>ISO 80601-2-61<br>ISTA 2A<br>ASTM D-4169 | Pass |
| Biocompatibility | ISO 10993-1 | Biocompatible |



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**$rSO_2$ Accuracy testing**: the critical sensor optics technology of the proposed devices remains unchanged from the predicate devices. $rSO_2$ accuracy is demonstrated through detailed device comparison, analysis and testing.

**Clinical testing:** the critical sensor optics technology of the proposed devices remains unchanged from the predicate devices. Thus prior clinical testing provided in K102715 is applicable for the proposed Model 8203CA and Model 8204CA sensors.

**Testing conclusion:** the proposed Model 8203CA and Model 8204CA sensors meet all acceptance criteria. Based on test results, analysis and comparison to the legally marketed predicates, the Model 8203CA and Model 8204CA sensors perform equivalently to the predicate sensors for their intended use.

**Summary of Substantial Equivalence:**

The Model 8203CA and Model 8204CA sensors have the following similarities to the predicate devices:

- Identical indications for use
- Identical intended use environments
- Identical patient population
- Same primary mode of operation
- Identical critical sensor optics technology
- Used with the same systems in same manner
- Perform equivalently to the same specifications
- Similar construction and materials

**Conclusion:**

No new questions of safety and effectiveness were raised. Based on the results of the above referenced testing, the same critical optics technology, results from safety and performance testing and analysis, and risk management assessment, Nonin Medical has determined that the proposed SenSmart Model 8203CA Regional Oximetry Sensor and SenSmart Model 8204CA Regional Oximetry Sensor are substantially equivalent to the predicate Nonin SenSmart Model 8003CA Regional Oximetry Sensor and SenSmart Model 8004CA Regional Oximetry Sensor and the proposed devices are safe for their intended use.



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