DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 6, 2017

Bluepoint Medical GmbH & Co. KG
% Stephen Gorski
President
Imagenix, Inc.
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K162014
Trade/Device Name: Nellcor Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 30, 2016
Received: January 04, 2016

Dear Stephen Gorski:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*

Device Name
Nellcor Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P

Indications for Use *(Describe)*
The Nellcor Flexible SpO2 Sensors, models FLEXMAX and FLEXMAX-P, are indicated for use with monitoring systems that use Nellcor OxiMax and Nellcor compatible pulse oximeters.

The Nellcor Flexible SpO2 Sensors are intended for use in non-invasive continuous or spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The sensor size range includes a large and small sensor. The sensors are intended for use on adult and pediatric (excluding infant and neonatal) patients weighing greater than 20kg.

The use environment may include: hospitals, hospital-type facilities, intra-hospital transport, mobile emergency medical applications including both ground and air transport, and home use. Transport environments may include intra-hospital transport and both ground and air emergency transport: road ambulances and fixed-wing aircraft and helicopters. The use is dependent upon the use environments specified for the monitoring system utilized in conjunction with the sensor.

The Nellcor Flexible SpO2 Sensors are for prescription use only.

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 in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Contact Person: Mr. Bernd Lindner

Position/Title: Managing Director

Date of Preparation: February 6, 2017

(2) **Trade Name:** Nellcor Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P

Common/Classification Name: OXIMETER;

Product Code(s): 21 CFR §870.2700; DQA

Class: Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K012891	Nellcor DS100A Finger Sensor (accessory part of OxiMax N595 Pulse Oximeter System)	Nellcor Puritan Bennett, Inc. (now Medtronic/Covidien)
K101690	SenTec SpO2 Soft Sensor (accessory part of SenTec Digital Monitoring System)	SenTec AG

Reason for Submission: New Device(s)

(4) **Description of Device:**

Bluepoint Medical's Nellcor-branded reusable Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P are pulse oximeter sensors designed and validated for compatibility with Nellcor pulse oximetry and monitoring systems.

Bluepoint Medical reusable Nellcor Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P are designed for the same functionality as the predicate device sensors, measuring functional oxygen saturation using the patient's finger as the measurement site. They are constructed with the following features:

- Unitary flexible silicone rubber housing containing the optical transmitter and detector
- Sensor and cable are immersible for cleaning and disinfection
- Jacketed and shielded medical grade cable with ferrite for EMC suppression
- Manufacturer specific connector with sensor labeling for compatibility with Nellcor pulse oximetry and monitoring systems

The reusable Nellcor Flexible SpO2 Sensors are offered in two models corresponding to two sizes:

- FLEXMAX: Regular Size, with 40 mm housing width
- FLEXMAX-P: Small Size, with 38 mm housing width

Additionally, two models are packaged specifically for homecare:

- FLEXMAX-HC: Flexible SpO2 finger Sensor, Regular, Homecare
- FLEXMAX-P-HC: Flexible SpO2 finger Sensor, Small, Homecare

The homecare sensor models with -HC designation are identical in all respects to their professional use counterparts, however the sensors are packaged to additionally include the Home Use Guide for lay users.

(5) Intended use:

The measurement of functional oxygen saturation of arterial hemoglobin (SpO_2) has been a standard of care in the USA for 20 years. Applications for pulse oximetry include continuous and spot-check monitoring in the hospital, hospital-type facilities, and critical care environments, as well as the environments of emergency medical transport monitoring and home care.

Indications for Use:

The Nellcor Flexible SpO2 Sensors, models FLEXMAX and FLEXMAX-P, are indicated for use with monitoring systems that use Nellcor OxiMax and Nellcor compatible pulse oximeters.

The Nellcor Flexible SpO2 Sensors are intended for use in non-invasive continuous or spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The sensor size range includes a large and small sensor. The sensors are intended for use on adult and pediatric (excluding infant and neonatal) patients weighing greater than 20kg.

The use environment may include: hospitals, hospital-type facilities, intra-hospital transport, mobile emergency medical applications including both ground and air transport, and home use. Transport environments may include intra-hospital transport and both ground and air emergency transport: road ambulances and fixed-wing aircraft and helicopters. The use is dependent upon the use environments specified for the monitoring system utilized in conjunction with the sensor.

The Nellcor Flexible SpO2 sensors are for prescription use only.

Discussion of Differences in Indications to the Predicate Devices:

The submitted device and referenced predicate devices have the following differences in their indication statements regarding pulse oximetry monitoring:

- For the submitted device, the monitoring is defined as: non-invasive continuous or spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate….. for use on adult and pediatric (excluding infant and neonatal) patients weighing greater than 20kg.
- For the SenTec type RSS sensor, the monitoring is defined as: continuous non-invasive monitoring of oxygen saturation, and pulse rate …. for patients weighing more than 20 kg.
- For the Nellcor DS100A Adult SpO2 Sensor, the monitoring is defined as: continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate …. for patients weighing greater than 40 kg.

The differences in the wording of the subject and predicate device indications for use are not critical to the intended use of the device as a pulse oximeter sensor and do not affect the safety and effectiveness of the device when used as labeled for the following reasons:

- Slight differences in terminology for the non-invasive monitoring of functional oxygen saturation and pulse rate are equivalent, i.e. all claims are readily understandable as referring to pulse oximeter monitoring.
- All devices claim continuous monitoring, the addition of spot-check monitoring to the subject device indications for use does not obviate continuous use and provides clarification that the device may be used for short periods of time as well.
- The subject device provides clarification regarding the weight range and patient population that the device can be applied on. The weight range of greater than 20 kg is the same as the SenTec type RSS sensor as described in the comparison table of technical features below.

Therefore, in consideration of the above, the differences identified are not critical to the intended use of the device as a pulse oximeter sensor and do not affect the safety and effectiveness of the device when used as labeled.

(6) Technological Characteristics:

The reusable Nellcor Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P utilize the same technological principles as the predicate devices to determine arterial oxygen saturation: arterially perfused tissue is illuminated sequentially by two wavelengths of light emitted by light emitting diodes (LED's), and the time varying absorbance of the tissue is measured from a silicon photodiode light sensor. This method is characteristic of the pulse oximeter sensors which are the subject of this submission as well as the predicate devices.

Comparison of Technological Features to Predicate Devices:

Product/Feature	Nellcor Flexible SpO2 Sensors models FLEXMAX/FLEXMAX-P	SenTec type RSS Reusable SpO2 Soft Sensors	Nellcor DS100A Adult SpO2 Sensor, Reusable
Manufacturer	Bluepoint Medical GmbH & Co. KG	SenTec AG	Nellcor Puritan Bennett, Inc. (now Covidien/ Medtronic)
Model Number(s)	FLEXMAX, FLEXMAX-P	RSS-L RSS-M RSS-S	DS100A
510(k) Number	(*pending this submission*)	**K101690**	**K012891**
Patient Population	Adult through pediatric (not infant or neonatal) patients	Adult through pediatric (not infant or neonatal) patients	Adult patients
Patient Weight Range	> 20kg	> 20kg	>40kg
Application Site	Finger	Finger, thumb, large toe, or little finger	Finger. Do not use the DS100A on a thumb or toe
Reusable	✓ YES	✓ YES	✓ YES
Monitoring System Compatibility	Nellcor OxiMax and Nellcor compatible pulse oximeters	SenTec, additionally Nellcor	Nellcor
Specified SpO2 measurement range	70-100%	70-100%	70-100%
SpO2 accuracy	ARMS ≤ 2.5	ARMS = 2.0	± 3 digits
Pulse rate measurement range	20-250 BPM	30-250 BPM	20-250 BPM (NOTE: function of monitor)
Pulse rate accuracy	± 3 BPM	± 3 BPM	± 3 digits
Optical Design	Transmissive Sensor	Transmissive Sensor	Transmissive Sensor
Housing Design	Sealed Unitary Silicone Tube type housing	Sealed Unitary Silicone Tube type housing	Rigid Finger Clip with floating spring hinge and inner silicone pads
Cable Length	90 cm	90 cm	90 cm
Connector Type	9 Pin male D sub connector	9 Pin male D sub connector	9 Pin male D sub connector
LED Drive Wiring	2 wire: to opposed RED/Infrared LED pair	2 wire: to opposed RED/Infrared LED pair	2 wire: to opposed RED/Infrared LED pair

As summarized above, the Bluepoint Medical Reusable Nellcor SpO2 Sensors models FLEXMAX/FLEXMAX-P utilize equivalent technological characteristics and specifications as the listed predicate devices.

(b) (1) **Non-Clinical Tests Submitted:**

FLEXMAX sensors were laboratory tested to current applicable standards for medical device electrical safety and electromagnetic compatibility as well as particular standards for pulse oximetry. Environmental and shock and vibration test levels addressed requirements for ground and air transport, including fixed-wing aircraft and helicopters, and home use. The following standards were utilized in compliance testing:

- Electrical safety testing per IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-1-2
- Testing for the home healthcare environment per IEC 60601-1-11
- Testing for the emergency medical services environment per IEC 60601-1-12
- Particular requirements for pulse oximeters per ISO 80601-2-61
- Environmental testing per the test levels specified in home healthcare and emergency medical services standards:IEC 60601-1-11; and IEC 60601-1-12
- Mechanical testing per the test levels specified in the pulse oximeter standard ISO 80601-2-61, and further specified in the emergency medical services standards IEC 60601-1-12

The sensors met the acceptance criteria for compliance to the standards.

The sensors (with a representative range of host monitors) were tested for pulse rate accuracy with a listed simulator per the following standard and guidance:

- Pulse simulator testing of testing of pulse rate per ISO 80601-2-61 and the FDA pulse oximeter guidance

The sensors met the acceptance criteria for pulse rate accuracy.

Risk management, risk and hazard analysis of the sensors was performed to the following standard:

- Application of risk management to medical devices per ISO 14971

The sensors met the acceptance criteria for residual risks.

Usability of the devices was evaluated and user testing was performed on a representative user population per the following standards and guidance:

- Usability testing per IEC 60601-1-6, IEC 62366, and the FDA Human Factors and Usability Guidance

The sensors met the acceptance criteria for usability.

Sensor patient contact materials were evaluated for biocompatibility. The tests were performed to the following standards and included the listed tests:

- Biocompatibility testing per ISO-10993-1, ISO-10993-5 and ISO-10993-10
- Cytotoxicity test - MEM elution assay using L-929 mouse fibroblast cells
- Intracutaneous irritation test
- Guinea pig maximization sensitization test

The sensor materials met the acceptance criteria for biocompatibility.

The sensors were evaluated for compatibility with the specified cleaning and disinfection agents, and for the efficacy of the specified high level disinfection agents per the following standards and technical guidance documents:

- ISO 15583-5, AAMI TIR12, AAMI TIR30, FDA Guidance for Reprocessing Medical Devices in Health Care Settings

The sensor materials met the acceptance criteria for cleaning and disinfection.

In summary, the sensors met test criteria for standards conformance to the applicable standards, pulse rate accuracy, usability, biocompatibility, and cleaning and disinfection. Residual risks met criteria for acceptability for the intended use.

(2) Clinical Tests Submitted:

Clinical testing of the sensors was performed on a representative range of host monitors to validate the accuracy of the sensors. A controlled hypoxia study was performed with arterial oxygen saturation determined by co-oximetry utilized as the reference method, per the following standard:

- Evaluation of clinical accuracy per ISO 80601-2-61, including informative Annex EE, and the FDA pulse oximeter guidance

Clinical testing was performed on healthy adult subjects under an institutionally approved protocol with subject informed consent. Clinical test results support the stated accuracy claims for the specified range of 70% to 100% SaO_2.

(3) Conclusions from Tests:

As described in (b)(1) and (b)(2) above, the reusable Nellcor Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P are equivalent to the predicate sensors as supported by compliance, laboratory, biocompatibility and clinical testing.

The results of all tests demonstrate that the reusable Nellcor Flexible SpO2 Sensors models FLEXMAX and FLEXMAX-P meet specified requirements for device compatibility and substantial equivalence to the referenced predicate devices.