April 27, 2020

Leadtek Research Inc.
Sharon Peng
Regulatory Affairs Specialist
18F, No.166, Jian-Yi Rd., Zhonghe Dist
New Taipei City, 23511 Tw

Re: K193350
Trade/Device Name: Leadtek Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 23, 2020
Received: April 8, 2020

Dear Sharon Peng:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K193350

Device Name
Leadtek Fingertip Pulse Oximeter

Indications for Use *(Describe)*
The Leadtek Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches to 0.9 inches) and for patients during no-motion condition.

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

K193350

This summary of 510(K) information is being submitted in accordance with the requirements of 21 CFR 807.92

1. Applicant Information

Applicant:	Leadtek Research Incorporation
Address:	18F, No.166, Jian-Yi Rd., Chung Ho Dist.
	23511 New Taipei City, Taiwan
Phone:	+886-2-8226-5800
Fax Number:	+886-2-8226-5801
Contact Person:	Sharon Peng
	Regulatory Affairs Specialist
Date Prepared:	March 26, 2020

2. Device Information

Proprietary Name:	Leadtek Fingertip Pulse Oximeter
Common Name:	Pulse Oximeter
Classification Name:	Oximeter
Regulatory Class:	Class II
Regulation Number:	21CFR 870.2700
Product Code:	DQA
Review Panel:	Anesthesiology

3. Predicate Device

Proprietary Name:	Onyx Vantage 9590
510(K) Number:	K112843
Manufacturer:	Nonin Medical Inc.

4. Intended Use

The Leadtek Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches to 0.9 inches) and for patients during no-motion condition.

5. Device Description

The main function of the Leadtek Fingertip Pulse Oximeter is to measure the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate as non-invasive spot checking. The Fingertip Pulse Oximeter determines the functional oxygen saturation of arterial hemoglobin (SpO2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine SpO2 reading and pulse rate. The characteristic of the device is a stand-alone device with 1 AAA Alkaline battery. It includes an OLED display screen and a warning or indicator function for abnormal readings.

6. Substantial Equivalence Information:

The intended use and test principle of Leadtek Fingertip Pulse Oximeter is similar to that of the predicates, Onyx Vantage 9590. The main function of Leadtek Fingertip Pulse Oximeter is to measure the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate as non-invasive spot checking by measuring the absorption of red and infrared light passing through perfused tissue.

The main differences between the proposed device and predicated device is that Leadtek Fingertip Pulse Oximeter has an input key for the operation and a warning/ indicator function which will show RED and make beep sounds when the value of SpO2 or pulse rate is out of the setting range. The power supply source is same as the predicates with only one battery. A comparison table between the proposed device and the predicated device is in the following below.

Item	**Proposed Device**	**Predicate Device**
Product Name	**Leadtek Fingertip Pulse Oximeter**	**Onyx Vantage 9590**
Model No.	**8D01B and 8D01C**	**Onyx 9590**
510(k) Information		
Regulation Number	870.2700	870.2700
Classification	Class II	Class II
Product Code	DQA	DQA
Indication for Use		
Statement	The **8D01B** and **8D01C** are intended	The **Nonin® Onyx Vantage 9590 Finger**

Item	Proposed Device	Predicate Device
Product Name	**Leadtek Fingertip Pulse Oximeter**	**Onyx Vantage 9590**
Model No.	**8D01B and 8D01C**	**Onyx 9590**
	for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches to 0.9 inches) and for patients during no-motion condition.	**Pulse Oximeter** is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on digits, including the thumb and toes, that are between 0.3 - 1.0 inch (0.8 -2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.
Population	adults and adolescent patients	adult and pediatric patients
Application site	Finger	Finger, thumb, and toes
Performance	normal condition	normal and low perfusion conditions
Stand-alone or module	stand-alone	stand-alone
Single use or not	multiple use	multiple use
Use environment	home and professional caring environment	home and professional caring environment
Comparison	The proposed device and the predicated device have the same intended use and classification. All changes in indications for use would not affect the safety and effectiveness. The **Leadtek Fingertip Pulse Oximeter** is substantially equivalent to the predicate device (K112843) concerning the same intended use.	
Test Principle		
Principle	Determine the functional oxygen saturation of arterial hemoglobin	Displays numerical values for functional oxygen saturation of arterial hemoglobin

Item	Proposed Device	Predicate Device
Product Name	**Leadtek Fingertip Pulse Oximeter**	**Onyx Vantage 9590**
Model No.	**8D01B and 8D01C**	**Onyx 9590**
	(SpO_2) and pulse rate by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine SpO_2 reading and pulse rate.	(SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine SpO_2 and pulse rate.
Wavelength	Dual wavelength LED (660 nanometers @ 0.8mW and 940 nanometers @ 1.2mW; both as max average	Dual wavelength LED (660 nanometers @ 0.8mW and 910 nanometers @ 1.2mW; both as max average
Comparison	The difference between the proposed device and the predicate device is the infrared wavelength. There is no additional question of safety and effectiveness as compared to the predicate device. The Leadtek Fingertip Pulse Oximeter is substantially equivalent to the predicated device (K112843) concerning the test principle.	
Energy		
Type	Battery	Battery
Battery	AAA Alkaline battery x 1	AAA Alkaline battery x 2
Comparison	There is no additional question of safety and effectiveness as compared to the predicate device raised by the battery. The **Leadtek Fingertip Pulse Oximeter** is substantially equivalent to the predicate device (K112843) concerning the energy source.	
Operation Features		
On/Off	Automatic turn on and off	Automatic turn on and off
Display	Full color OLED	LED
Input Key	A 5-directional key (**8D01B)** or a single push-down (**8D01C)** key	None
Warning / Indicator	**8D01B:** Audio and visual warning **8D01C:** Visual indicator	Visual indicator
Warning /	**8D01B**:	3 color pulse quality indicator to provide

Item	Proposed Device	Predicate Device
Product Name	**Leadtek Fingertip Pulse Oximeter**	**Onyx Vantage 9590**
Model No.	**8D01B and 8D01C**	**Onyx 9590**
Indicator Function	Appear red color with beep sounds when SpO2 and pulse rate out of the setting range. ▪ Low SpO_2 warning: default 87%; setting range: 50% to 95% ▪ High SpO_2 warning: default off; setting range: 80% to 100% ▪ Low HR warning: default off; setting range: 30 to 110 bpm ▪ High HR warning: default off; setting range: 75 to 250 bpm	assurance of reading quality ▪ Green Light: Good Reading ▪ Yellow Light: Fair Reading ▪ Red Light: Poor Reading.
Display Rotation	Yes	None
Comparison	The differences of operation features will not be considered as a NSE between the proposed device and the predicate device. The **Leadtek Fingertip Pulse Oximeter** is substantially equivalent to the predicate device (K112843) concerning the technological characteristics.	
General Specification		
Usage Life	> 24 hrs typical operation under default setting	6,000 spot checks or 36 hours of operation
Operating Temp.	5 ºC to 40 ºC (41 ºF to 104 ºF)	-5 ºC to 40 ºC (23 ºF to 104 ºF)
Storage Temp.	-30ºC to 70 ºC (-22 ºF to 158 ºF)	-40ºC to 70 ºC (-40 ºF to 158 ºF)
Humidity	10% to 90%, non-condensing for both operating and storage	10% to 90%, non-condensing for operating 10% to 95%, non-condensing for storage
Atmospheric	700 hPa - 1013 hPa for both operating	Up to 4 atmospheres

Item	Proposed Device	Predicate Device
Product Name	**Leadtek Fingertip Pulse Oximeter**	**Onyx Vantage 9590**
Model No.	**8D01B and 8D01C**	**Onyx 9590**
Pressure	and storage	
Water Resistance	IP22	IP32
Classification		
Applied Part	Type BF	Type BF
Safety	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2
Harmonized Standard	ISO 80601-2-61	ISO 80601-2-61
Mode of Operation	Spot checking	continuous monitoring
Appearance		
Weight	weight without battery: 26g (0,92 ounces)	less than 60g (2 ounces)
Size	L67.5 mm (2.63”) x W38 mm (1.48”) x H25 mm (0.98”)	L55.9 mm (2.2”) x W33 mm (1.3”) x H32.3 mm (1.27”)
Comparison	The differences of general specification and appearance will not be considered as a NSE between the proposed device and the predicate device. The **Leadtek Fingertip Pulse Oximeter** is substantially equivalent to the predicate device (K112843) concerning the general specification and appearance.	
Pulse Oximetry and Heat Rate Specification		
Range	0% to 100%	0% to 100%
Resolution	1%	1%
Accuracy	70% to 100% range ± 2%, less than 70% are unspecified	70% to 100% range ± 2%, less than 70% are unspecified
Heat Rate Specification		
Range	30 to 250 bpm	18 to 321 bpm
Resolution	1 bpm	1 bpm
Accuracy	±1 bpm or ±1%, whichever is greater	20 to 250 bpm ±3 digits

Item	Proposed Device	Predicate Device
Product Name	**Leadtek Fingertip Pulse Oximeter**	**Onyx Vantage 9590**
Model No.	**8D01B and 8D01C**	**Onyx 9590**
Comparison	The difference of Heart Rate Specification will not be considered as a NSE between the proposed device and the predicate device. The **Leadtek Fingertip Pulse Oximeter** is substantially equivalent to the predicate device (K112843) concerning the performance specification.	

7. Functional and Safety Testing:

The Leadtek Fingertip Pulse Oximeter is designed and conducted in accordance with the related standards. The following tests were performed to verify and validate that Leadtek Fingertip Pulse Oximeter meets all requirements of related standards and demonstrates substantial equivalence to the predicates.

Electrical Safety and EMC Testing

The laboratory tests of electrical safety, electromagnetic compatibility, and reliability testing were conducted and show that the proposed device complies with IEC 60601-1:2012 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 compatibility – Requirements and tests, IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment, and ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Biocompatibility Testing

The biocompatibility testing for Leadtek Fingertip Pulse Oximeter was in accordance with ISO 10993-1:2009 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process” as recognized by FDA. The studies of cytotoxicity, skin sensitization, and skin irritation were performed and show that the skin contacting materials do not cause the potential risks.

Software Verification and Validation

Software verification and validation were provided in compliance with FDA Guidance for the Content of the Premarket Submission for Software Contained in Medical Devices. These

verifications and validations demonstrate that Leadtek Fingertip Pulse Oximeter work functionally. The software for the device is considered as a “moderate” level of concern, which is identical to the predicate devices. A failure or latent flaw in the software could not directly cause serious injury or death to the patient or operator, but a non-serious injury could occur. According to FDA Guidance document, the software validation documentation summarized the required for a Moderate level of concern device.

Cleaning Validation

Cleaning and disinfection validations were executed in accordance with FDA Guidance “Reprocessing Medical Device in Health Care Setting: Validation Methods and Labeling”

The performance of Leadtek Fingertip Pulse Oximeter will not be affected after multiple cleaning and disinfection procedures as illustrated in user manual.

Performance Testing

The laboratory and clinical evaluations for the performance of Leadtek Fingertip Pulse Oximeter demonstrate that the modifications do not raise different questions of safety and effectiveness. The root-mean-square (Arms) was used to analyze the accuracy of Leadtek Fingertip Pulse Oximeter, per ISO 80601-2-61:2011, the SpO2 accuracy results demonstrate that the root-mean-square (Arms) value of Leadtek Fingertip Pulse Oximeter is less than 2% within the range 70% - 100%.

Clinical Evaluation

The functional oxygen saturation (SpO2) measurements were validated in accordance with ISO 80601-2-61. The clinical evaluation for SpO2 accuracy was conducted on healthy male and female, light to dark skinned subjects, and total 10 subjects were enrolled. The SpO2 accuracy data was calculated using the root-mean-square (Arms); the performance results showed the Leadtek Fingertip Pulse Oximeter has an Arms of 1.72 during steady state conditions over the range of 70-100% and it is also in compliance with the specified performance claimed by the manufacturer.

8. Conclusion

The Leadtek Fingertip Pulse Oximeter has the same intended use and similar characteristics as that of the predicate device manufactured by Nonin Medical Inc. and cleared by FDA under K112843. Based on the information contained in this submission demonstrate that any different characteristics do not raise different questions of safety and effectiveness.