September 1, 2021

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

Re: K210032
Trade/Device Name: Leadtek Fingertip Pulse Oximeter (Wireless)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 26, 2021
Received: August 2, 2021

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)*
K210032

Device Name
Fingertip Pulse Oximeter (Wireless)

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter (Wireless) 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.

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510(k) Summary

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

1. General Information

Applicant:	Leadtek Research Incorporation 18F, No.166, Jian-Yi Rd., Chung Ho Dist. 23511 New Taipei City, Taiwan Phone: +886-2-8226-5800 Fax: +886-2-8226-5801
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Date Prepared:	December 21, 2020

2. Device Information

Proprietary Name:	Fingertip Pulse Oximeter (Wireless)
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:	Fingertip Pulse Oximeter
510(K) Number:	K193350
Manufacturer:	Leadtek Research Inc.

4. Intended Use

The Fingertip Pulse Oximeter (Wireless) 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 Fingertip Pulse Oximeter (Wireless) is to measure the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate as non-invasive spot checking monitoring. The subject device 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.

The Fingertip Pulse Oximeter (Wireless) is also built in with a Bluetooth low energy (BLE) function to perform data transmission.

6. Substantial Equivalence Information:

The intended use and test principle of Fingertip Pulse Oximeter (Wireless) is the same that used in the predicate devices, Fingertip Pulse Oximeter cleared under k193350. The main function of Fingertip Pulse Oximeter (Wireless) 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. No changes of intended use and technological characteristics support the substantial equivalence of the subject device to the predicate.

As compared to the predicate device, the main modification of the subject device is that Fingertip Pulse Oximeter (Wireless) uses Bluetooth Low Energy (BLE) technology to transfer the measurement results from the oximeter to a mobile device or PC tablet enabled Bluetooth function. The Bluetooth icon will light up on the oximeter display when a connection is established successfully. The data of the oximeter will be synchronized with the enable device since the successful connection. The verification and validation tests were found to support that wireless transmission function will not raise different questions of safety and effectiveness.

Table 6-1. A comparison table between subject and predicate device

Item	Subject Device	Predicate Device
Product Name	**Fingertip Pulse Oximeter (Wireless)**	**Fingertip Pulse Oximeter**
Model No.	**8D01H and 8D01I**	**8D01B and 8D01C**
510(k) Information		
Regulation Number	870.2700	870.2700
Classification	Class II	Class II
Product Code	DQA	DQA
Comparison	**Unchanged as previous submission**	
Indication for Use		
Intended Use	Fingertip Pulse Oximeter (Wireless) 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.	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.
Population	adults and adolescent patients	adults and adolescent patients
Application site	Finger	Finger
Performance	normal condition	normal condition
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	**Unchanged as previous submission**	
Test Principle		
Principle	Determine the functional oxygen	Determine the functional oxygen

Item	Subject Device	Predicate Device
Product Name	**Fingertip Pulse Oximeter (Wireless)**	**Fingertip Pulse Oximeter**
Model No.	**8D01H and 8D01I**	**8D01B and 8D01C**
	saturation of arterial hemoglobin (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.	saturation of arterial hemoglobin (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.
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 880 nanometers @ 1.2mW; both as max average)
Comparison	**Unchanged as previous submission**	
Energy		
Type	Battery	Battery
Battery	AAA Alkaline battery x 1	AAA Alkaline battery x 1
Comparison	**Unchanged as previous submission**	
Operation Features		
On/Off	Automatic turn on and off	Automatic turn on and off
Display	Full color OLED	Full color OLED
Input Key	A 5-directional key (8D01H) or a single push-down (8D01I) key	A 5-directional key (8D01B) or a single push-down (8D01C) key
Warning / Indicator	8D01H: Audio and visual warning 8D01I: Visual indicator	8D01B: Audio and visual warning 8D01C: Visual indicator
Warning / Indicator Function	8D01H: 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%	8D01B: 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%

Item	Subject Device	Predicate Device
Product Name	**Fingertip Pulse Oximeter (Wireless)**	**Fingertip Pulse Oximeter**
Model No.	**8D01H and 8D01I**	**8D01B and 8D01C**
	▪ 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 8D01I: Appear red color when SpO2 is lower than 87%.	▪ 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 8D01C: Appear red color when SpO2 is lower than 87%.
Display Rotation	Yes	Yes
Wireless Connection	BLE BT 4.0	None
Comparison	**The differences of operation features is an additional Bluetooth module with data transmission. With the VIEW TRACKER app, "8D01" Leadtek Fingertip Pulse Oximeter (Wireless) can transmit the real-time heart rate, SpO2, and IR waveform to the compatible mobile device for the sole purpose of data recording, daily review, and IR waveform display, not for continuous monitoring. The software is validated according to FDA's Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. The wireless testing is conducted according to FDA's Guidance Radio Frequency Wireless Technology in Medical Devices. The difference does not raise different questions of safety and effectiveness.**	
General Specification		
Usage Life	> 18 hrs typical operation under default setting	> 24 hrs typical operation under default setting
Operating Temp.	5 ºC to 40 ºC (41 ºF to 104 ºF)	5 ºC to 40 ºC (41 ºF to 104 ºF)
Storage Temp.	-30ºC to 70 ºC (-22 ºF to 158 ºF)	-30ºC to 70 ºC (-22 ºF to 158 ºF)

Item	Subject Device	Predicate Device
Product Name	**Fingertip Pulse Oximeter (Wireless)**	**Fingertip Pulse Oximeter**
Model No.	**8D01H and 8D01I**	**8D01B and 8D01C**
Humidity	10% to 90%, non-condensing for both operating and storage	10% to 90%, non-condensing for both operating and storage
Atmospheric Pressure	700 hPa - 1013 hPa for both operating and storage	700 hPa - 1013 hPa for both operating and storage
Water Resistance	IP22	IP22
Comparison	**The differences of operation features is the usage life for supporting wireless communication and it will not be considered as a NSE between the subject and predicate device. The Fingertip Pulse Oximeter (Wireless) is substantially equivalent to the predicate device (K193350) concerning the general specification.**	
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	Spot checking
Comparison	**Unchanged as previous submission**	
Appearance		
Weight	weight without battery: 26g (0,92 ounces)	weight without battery: 26g (0,92 ounces)
Size	L67.5 mm (2.63”) x W38 mm (1.48”) x H25 mm (0.98”)	L67.5 mm (2.63”) x W38 mm (1.48”) x H25 mm (0.98”)
Comparison	**Unchanged as previous submission**	
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

Item	Subject Device	Predicate Device
Product Name	**Fingertip Pulse Oximeter (Wireless)**	**Fingertip Pulse Oximeter**
Model No.	**8D01H and 8D01I**	**8D01B and 8D01C**
Comparison	**Unchanged as previous submission**	
Heat Rate Specification		
Range	30 to 250 bpm	30 to 250 bpm
Resolution	1 bpm	1 bpm
Accuracy	±1 bpm or ±1%, whichever is greater	±1 bpm or ±1%, whichever is greater
Comparison	**Unchanged as previous submission**	

7. Functional and Safety Testing:

The Fingertip Pulse Oximeter (Wireless) is designed and conducted in accordance with the related standards. The following tests were performed to verify and validate that Leadtek Fingertip Pulse Oximeter (Wireless) 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 subject 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 skin contacting materials used with the subject device are the same that used for the predicate device under k193350. These materials were evaluated for biocompatibility testing 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 the subject device work functionally and the software for the device is considered as a "moderate" level of concern, as defined by the FDA guidance, and it 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. According to FDA Guidance document, the software validation documentation summarized the required for a Moderate level of concern device and the test results are found to support the substantial equivalence of the subject device.

Coexistence Testing

Coexistence testing was performed according to IEEE/ANSI C63.27:2009 American National Standard for Evaluation of Wireless Coexistence, AAMI TIR69:2017 Risk Management radio-frequency wireless coexistence for medical devices and systems, and FDA Guidance for Radio Frequency Wireless Technology in Medical Device to demonstrate that the subject device is able to coexist with interfering networks in the 2.4 GHz ISM band and the communication links for the subject device can coexist with BLE as the interfering network operating at maximum throughput and minimum transmit power. The wireless coexistence and the security of wireless data is within the limits declared in accordance with the characteristics of the subject device.

Non-clinical Performance Testing

The laboratory evaluations for the performance of the subject device was conducted to ensure the modification do not change the performance that root-mean-square (Arms) value is less than 2% within the range 70% - 100% and do not raise different questions of safety and effectiveness.

Clinical Testing

There is no change to the subject device in pulse oximetry algorithm since the subject device use the same test principle and measuring technology as the predicate device. A clinical study was conducted on the predicate device for K193350 clearance to demonstrate the safety and performance and additional clinical testing of the subject device performance is not required necessary to support the substantial equivalence.

8. Conclusion

The Fingertip Pulse Oximeter (Wireless) has the same intended use and technology and similar characteristics as that of the predicate device cleared by FDA under K193350 and manufactured

by Leadtek Research Inc. Based on the information contained in this submission demonstrate that the subject device is substantially equivalent to the predicate device and any different characteristics do not raise different questions of safety and effectiveness.