July 24, 2020

Remote Diagnostic Technologies Ltd., a Philips Company
% Meaghan Bailey
Executive Director
NSF Health Sciences, LLC
2001 Pennsylvania Avenue NW, Suite 950
Washington, District of Columbia 20006

Re: K200849
Trade/Device Name: TEMPUS LS - MANUAL
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-Defibrillator (Including Paddles)
Regulatory Class: Class II
Product Code: LDD, DRO, DPS, LIX
Dated: June 26, 2020
Received: June 26, 2020

Dear Meaghan Bailey:

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,

Jennifer Shih
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K200849

Device Name
TEMPUS LS - MANUAL

Indications for Use *(Describe)*
The TEMPUS LS - MANUAL is a multi-function, portable device that is capable of providing defibrillation therapy, non-invasive external pacing, displaying ECG, and CPR feedback in hospital and pre-hospital settings. It is to be used by qualified medical health care professionals trained in the use and operation of the device and qualified by training in advanced cardiovascular life (ACLS) support.

Manual Defibrillation
In Manual Defibrillation mode, the TEMPUS LS - MANUAL is indicated for victims of cardiac arrest where there is apparent lack of circulation as indicated by these three conditions:

- Unconsciousness
- Absence of breathing, and
- Absence of pulse.

This product should be used only by qualified medical personnel for terminating ventricular fibrillation and ventricular tachycardia.

Defibrillation is indicated for adult and pediatric patients. When a victim is less than 8 years of age, or weighs less than 55 lbs. (25kg), the TEMPUS LS - MANUAL should be used with the Tempus Pediatric Electrodes or in the device's pediatric mode with the Tempus Adult Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

Cardioversion
The TEMPUS LS – MANUAL may be used for synchronized cardioversion to terminate atrial fibrillation (AF) or ventricular tachycardia (VT) by using the R-wave of the patient's ECG as a timing reference. A qualified user trained in the operation of the device must decide when synchronized cardioversion is appropriate. Cardioversion is indicated for adult and pediatric patients.

External Pacing
The TEMPUS LS – MANUAL is indicated for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation. The purposes of pacing include:

- Resuscitation from standstill or bradycardia of any etiology.
- As a standby when standstill or bradycardia might be expected.

External pacing is indicated for adult and pediatric patients.

ECG Display
The TEMPUS LS – MANUAL is intended to display a patient's ECG from a 3- or 4- lead wire ECG patient cable. It is indicated for use in adult or pediatric patients for attended monitoring of the patient's ECG signal (e.g., before starting demand pacing or after successful defibrillation).

CPR Feedback
The TEMPUS LS – MANUAL may be supplied with an optional CPR feedback sensor, which is intended to provide

visual and audio feedback to encourage rescuers to perform CPR in accordance with AHA/ERC guidelines for chest compression rate and depth. It is indicated for use on adult and pediatric patients ≥ 8 years of age or weighing ≥ 25 kg / 55 lbs.

CPR Feedback is not indicated for use on neonatal and pediatric patients under 8 years of age or weighing less than 25 kg/55 lbs.

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

Submitter Information

Applicant

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Submitter

Name:	NSF Health Sciences
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Contact Person:	Meaghan Bailey, Executive Director
Phone No:	202-445-0577
Email:	mbailey@nsf.org
Date Summary Prepared:	July 22, 2020

Device Identification

Device Name:	TEMPUS LS – MANUAL
Common Name:	Low-Energy Defibrillator
Classification:	II
Product Code:	LDD
Secondary Product Codes:	DRO, LIX, DPS
Regulation Number:	21 CFR 870. 5300

Predicate Device(s)

Primary Predicate:	ZOLL E-Series ALS (K140502)
Secondary Predicate:	Philips HeartStart XL (K021453)
	Philips HeartStart XL+ (K133659)

Device Description

The TEMPUS LS – MANUAL is a compact, lightweight, portable electromedical device that contains a direct current (DC) defibrillator capable of delivering up to 200 joules of electrical energy to a patient through self-adhesive external electrode pads. The device is intended for use by advanced cardiac life support (ACLS) trained health care professionals in hospital and pre-hospital settings to provide defibrillation therapy, non-

invasive external pacing, cardiopulmonary resuscitation (CPR) feedback, and non-alarming electrocardiograph (ECG) monitoring. The device is intended for prescription-use only. The unit is powered by a rechargeable lithium-ion battery which is recharged when connected to a mains power supply. The unit incorporates a color LCD display that displays information related to a clinical intervention. The trained user may select an energy level between 1 - 200 joules and deliver a shock in either an asynchronous mode of delivery or through synchronized cardioversion using the patient's R-wave as a timing reference for the shock.

The device provides non-invasive transcutaneous pacing in either fixed or demand modes of operation through the same self-adhesive pads used in manual defibrillation. In addition, the device incorporates an audible metronome to guide a user as to the correct rate at which chest compressions should be administered in accordance with current American Heart Association (AHA) resuscitation guidelines. The device may be supplied with an optional cardiopulmonary resuscitation (CPR) feedback sensor which assists caregivers during CPR in delivering chest compressions at a rate and depth in compliance with current AHA guidelines. The device may also be paired to a compatible external device via a secure wireless communications protocol called Tempus Data Link (TDL) to export event data (without patient identifiers) at the convenience of the user.

TEMPUS LS – MANUAL features list:

- Manual mode defibrillation delivered in a Bi-phasic Truncated Exponential (BTE) waveform
- 1 – 200 joule user-configurable energy levels
- Synchronized cardioversion
- External pacer (fixed & demand modes)
- CPR metronome & optional sensor providing feedback on CPR rate and CPR depth
- 3-lead wire and 4-lead wire ECG monitoring (non-alarming)
- Export of event data via Bluetooth and USB cable

The following accessories are provided with the TEMPUS LS – MANUAL:

- External electrode pads (adult/child, pediatric)
- 10.8 V Lithium-ion battery
- Mains power supply unit with mains cable
- 3-lead or 4-lead wire ECG cable (optional)
- CPR feedback sensor & disposable adhesive securing pads (optional)

Indications for Use

The TEMPUS LS – MANUAL is a multi-function, portable device that is capable of providing defibrillation therapy, non-invasive external pacing, displaying ECG, and CPR feedback in hospital and pre-hospital settings. It is to be used by qualified medical health care professionals trained in the use and operation of the device and qualified by training in advanced cardiovascular life (ACLS) support.

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CPR Feedback is not indicated for use on neonatal and pediatric patients under 8 years of age or weighing less than 25 kg/55lbs.

Summary of Technological Characteristics

The TEMPUS LS – MANUAL utilizes features and technologies substantially equivalent to the primary (K140502) and secondary (K021453 and K133659) predicate devices.

The intended use, indications for use, and technological features provided by the TEMPUS LS – MANUAL (subject device) are substantially equivalent to those provided by the primary predicate, the ZOLL E-Series ALS (K140502). The fundamental technological characteristics of the TEMPUS LS – MANUAL and ZOLL E-Series ALS are also the same in that both devices use a biphasic waveform for defibrillation therapy.

The electrical waveform delivered in manual defibrillation is substantially equivalent to the biphasic truncated exponential (BTE) waveform utilized by the Philips HeartStart XL (K021453). The electrical waveform delivered in non-invasive pacing therapy is substantially equivalent to the monophasic rectilinear waveform utilized by the Philips HeartStart XL+ (K133659) device.

Based on the information provided in this premarket notification, Remote Diagnostic Technologies Limited concludes that the TEMPUS LS – MANUAL defibrillator is substantially equivalent to the predicate devices. See **Tables 1** and **2** below for a more detailed summary of substantial equivalence between the TEMPUS LS – MANUAL subject device and the predicate devices.

Table 1: Comparison of Technological Characteristics with ZOLL E-Series ALS (K140502)

	ZOLL E-Series ALS (K140502)	TEMPUS LS – MANUAL
TECHNOLOGICAL CHARACTERISTICS - GENERAL		
Indications for Use General Description	Multifunctional, portable electronic device – low energy defibrillator	Identical
Size	13.1" (W) 10.5" (D) 5.75" (H)	6.4" (W) 3.7" (D) 7.8" (H)
Weight	13.2 lbs	4.5 lbs
Ingress Protection	IP34	IP65
Operating Temperature	0˚ C to 55˚C	0˚C to 50˚C
Operating Pressure	594 to 1060 mBar	540 to 1060 mBar
Shock & Vibration	MIL-STD-810	Identical
Display Type	Color Liquid Crystal Display (LCD)	Identical
Screen Size	5.6 inches diagonally	5.7 inches diagonally
Electrical Safety Standard	IEC 60601-1	Identical
EMC Standard	IEC 60601-1-2 RTCA DO-160	IEC 60601-1-2 RTCA DO-160G Cat. M and R
Defibrillator Standard	IEC/EN 60601-2-4	Identical
ECG Standard	IEC 60601-2-27	Identical
TECHNOLOGICAL CHARACTERISTICS – DEFIBRILLATION AND CARDIOVERSION		
Manual Defibrillation Modes	Asynchronous manual Synchronous manual (cardioversion)	Identical
Output Energy	1 - 200 Joules into a 50 Ohm load	Identical
Defibrillation Waveform	Biphasic Rectilinear	Biphasic Truncated Exponential
TECHNOLOGICAL CHARACTERISTICS - PACING		
Modes	Fixed Demand	Identical
Fixed-mode principle	Use configurable; pre-set intervals; independent of intrinsic cardiac activity	Identical
Demand-mode principle	Use configurable; triggers when heart rate falls below target	Identical
Pacing delivery	Multifunction electrode pads	Identical
Pacing waveform	Monophasic Rectilinear, constant current, 40 milliseconds	Monophasic Rectilinear, constant current, 20 milliseconds
Pulse Amplitude	5 mA to 140 mA ±5% or 5 mA, whichever is greater	10 mA to 200 mA ± 10% or 5 mA, whichever is greatest
Pacing Rate	30 ppm to 180 ppm ± 1.5%	40 ppm to 180 ppm ± 1.5%
TECHNOLOGICAL CHARACTERISTICS – ECG MONITORING		
Standard	IEC 60601-2-27:2011	Substantially Equivalent For attended monitoring only, only technical alerts
Patient Connection	ECG cable	Identical

	ZOLL E-Series ALS (K140502)	TEMPUS LS – MANUAL
	Multifunction electrode pads	
Protection	Fully isolated, defibrillation-protected	Identical
Heart Rate Display	Digital readout on display	Identical
Heart Rate Range	0 to 300 bpm with accuracy ± 5% bpm	Substantially Equivalent 15 to 350 bpm with accuracy ± 10% bpm or 5 bpm, whichever is greater
Heart rate averaging	Averages the interval between the last 5 detected beats	Substantially Equivalent Averages the interval between the last 4-16 detected beats (user configurable)
Bandwidth	0.05 Hz – 150 Hz (-3 dB)	Identical
Tall T-wave rejection	< 1.0 mV	Substantially Equivalent < 0.8 mV
Pacemaker detection	± 2 mV to ± 700 mV 0.1 ms to 2 ms width	Identical
Reaction to irregular rhythm	A1: 40 bpm A2: 60 bpm A3: 120 bpm A4: 90 bpm	Substantially Equivalent per 60601-2-27 A1: 80 bpm A2: 60 bpm A3: 120 bpm A4: 90 bpm
Alarms	Yes	Yes, for technical alerts

Table 2: Comparison of waveform characteristics with Philips HeartStart XL (K021453) and Philips HeartStart XL+ (K133659)

	Philips HeartStart XL	HeartStart XL+	TEMPUS LS – MANUAL
Defibrillation Waveform	Biphasic truncated exponential	N/A	Biphasic truncated exponential
Pacing Waveform	N/A	Monophasic Rectilinear, constant current, 20 milliseconds duration	Monophasic Rectilinear, constant current, 20 milliseconds duration

Safety and Performance Data

The Tempus LS - MANUAL was evaluated via non-clinical safety and performance testing to demonstrate that the device met pre-established acceptance criteria and/or the requirements of FDA recognized consensus standards, and testing demonstrates substantially equivalence to the predicate devices.

Table 3: Summary of Performance Testing

Performance Testing	Summary
Sterilization and shelf-life	Non-sterile device and accessories 36-month shelf-life for defibrillator electrode pads, meeting requirements for electrical testing per 60601-2-4 24-month shelf-life for CPR feedback sensor securing pads
Biocompatibility	IEC 10993 testing met requirements for defibrillator electrode pads and CPR feedback sensor securing pads
Electrical safety	IEC 60601-1 testing met requirements of the standard
Electromagnetic compatibility	IEC 60601-1-2, RTCA DO 160G and AIM 7351731 and wireless coexistence testing met requirements
Software	Appropriate documentation for Major level of concern SW, including verification and validation testing at the unit, integration and system

	levels; demonstration of adequate cybersecurity risk control measures
Performance Testing – Bench	Bench testing was performed to evaluate the performance of the TEMPUS LS-MANUAL, inclusive of defibrillation, synchronized cardioversion, CPR metronome, pacing, and ECG display. The performance of the accessories including the CPR feedback sensor, electrode pads, ECG leads, power management was also evaluated. Furthermore, environmental performance, including vibration and shock, altitude, decompression and pressure, and climate, was evaluated. The tests showed passing results and the device is considered compliant with applicable standards (IEC 60601-2-4, IEC 60601-2-27; IEC 60601-1-8, AAMI EC53; IEC 60601-1-12; MIL-STD-810G; IEC 62133; UN 38.3; ASTM D4169-16)
Performance Testing – Human Factors	A human factors validation testing involving 15 participants representing intended users was performed to evaluate the usability of the TEMPUS – LS MANUAL in its intended use environment (pre-hospital; in-hospital). The study demonstrated that users were able to successfully and safely use the device.

Clinical evidence was not necessary to demonstrate substantial equivalence.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Remote Diagnostic Technologies Limited conclude that the TEMPUS LS – MANUAL defibrillator described in this pre-market notification is substantially equivalent to the predicate devices.