December 14, 2018

Seaward Group
% Robert Steurer
Principal Consultant
Steurer Consulting Group
800 Blue Quail Rd
Keller, Texas 76248

Re: K182905
Trade/Device Name: UniPulse 400
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator Tester
Regulatory Class: Class II
Product Code: DRL
Dated: October 12, 2018
Received: October 16, 2018

Dear Robert Steurer:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica E. Paulsen -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182905

Device Name

UniPulse 400

Indications for Use *(Describe)*

The UniPulse 400 Defibrillator/Pacemaker Analyzer is used to determine that a defibrillator and a defibrillator equipped with transcutaneous pacemaker capability are performing within their performance specifications through the measurement of energy output. The UniPulse 400 is intended to be used in the laboratory environment, outside of the patient care vicinity and is not intended to be used on patients or to test devices while connected to patients.

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."

Submission Date: October 12, 2018

Submitter: Rigel Medical, a Seaward Group company
15-18 Bracken Hill,
South West Industrial Estate,
Peterlee, Co. Durham, SR8 2SW,
United Kingdom

Submitter Contact: Rigel Medical, a Seaward Group company
15-18 Bracken Hill,
South West Industrial Estate,
Peterlee, Co. Durham, SR8 2SW,
United Kingdom
Name: Jim Wallace
Rigel Medical, a Seaward Group company
Phone: +44 (0)191 5878724
Fax: +44 (0) 191 586 0227
Email: JimW@seaward.co.uk

Application Correspondent: Bob Steurer
Principal Consultant
Steurer Consulting Group
800 Blue Quail Rd.
Keller, TX 76248
steurerbob@gmail.com
+1 (425) 358-1072

Manufacturing Site: Rigel Medical, a Seaward Group company
15-18 Bracken Hill,
South West Industrial Estate,
Peterlee, Co. Durham, SR8 2SW,
United Kingdom

Trade Name: UniPulse 400

Common Name: Defibrillator Analyzer

Classification Name: Defibrillator Tester

Primary Classification Regulation: 21 CFR §870.5325

Primary Product Code: DRL

Substantially Equivalent Devices:

New Device	*Predicate 510(k) Number*	*Predicate Manufacturer/Model*
Rigel Medical UniPulse 400 Defibrillator Analyzer	K072114	Fluke Biomedical Impulse 7000dp Defibrillator Analyzer

Device Description: The Rigel Medical UniPulse 400 is a portable, rechargeable battery operated (with AC Adapter) defibrillator tester used to determine that a defibrillator and a defibrillator with a transcutaneous pacemaker function perform to their published performance specifications. The UniPulse 400 is connected to a defibrillator output and is used to measure the output energy delivered from the device into a standard resistive test load. It also provides waveform information on its integrated display. For pacemaker testing, a variable load from 50 to 1600 ohms is available in 50-ohm steps. Defibrillator paddles are connected directly to the UniPulse 400 for hands free operation, or to contact plates if using the paddles. When the defibrillator is discharged, the UniPulse 400 will display the energy delivered. Included in the UniPulse 400 is an ECG simulator with normal sinus rhythm and arrhythmia simulation to trigger automated defibrillation.

UniPulse 400 is used by biomedical and/or clinical engineers to verify performance of defibrillators used in their hospital. The UniPulse 400 provides statistical data measured from the device and can communicate to an external Bluetooth printer and a PC / Laptop via Bluetooth and USB.

Intended Use: The UniPulse 400 Defibrillator/Pacemaker Analyzer is used to determine that a defibrillator and a defibrillator equipped with transcutaneous pacemaker capability are performing within their performance specifications through the measurement of energy output. The UniPulse 400 is intended to be used in the laboratory environment, outside of the patient care vicinity and is not intended to be used on patients or to test devices while connected to patients.

Technology Comparison: The Rigel UniPulse 400 employs the same technological characteristics as the predicate device.

Characteristic	Predicate Device – Impulse 7000dp	UniPulse 400
Load resistance	50 ohm	Same
Battery Operation	Internal rechargeable NiMH batteries with AC adapter	Same
Defibrillator waveform compatibility	Compatible with mono-phasic, bi-phasic, and pulsed waveforms	Same
Defibrillator Test Connections	Through integrated paddle connection plates or you can connect directly through accessory cable.	Same – Connect directly through accessory cable or paddle connections available through accessory paddle box
ECG Simulator with Arrhythmia output capability	Yes	Same
Data download	USB connection to PC	Same
Waveform Display	Through connected PC	Same, can also show on built-in display
Pacemaker Analysis	Demand and asynchronous test	Same
Pacemaker variable load	50 to 1500 ohms in 50-ohm steps	Different - 50 to 1600 ohms in 50-ohm steps

Summary of Performance Testing:

Sterilization and Shelf-life

The Rigel Medical UniPulse 400 is not provided sterile. The Rigel Medical UniPulse 400 does not have a shelf-life.
Therefore, this section is not applicable.

Biocompatibility

The Rigel Medical UniPulse 400 does not directly nor indirectly contact the patient. Therefore, this section is not applicable.

Software Testing

The Rigel Medical UniPulse 400 was designed and developed according to Rigel Medical's internal software development process. The Rigel Medical UniPulse 400 was tested using verification and validation methods, the results of which indicate the Rigel Medical UniPulse 400 complies with its specifications.

Electrical Safety

The Rigel Medical UniPulse 400 was tested for performance in accordance with the following standard:

- BS EN 61010-1-2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements,
- BS EN 61010-2-030:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-30 Particular requirements for testing and measuring circuits

Test results indicate the Rigel Medical UniPulse 400 complies with its specifications.

Electromagnetic Compatibility Testing

The Rigel Medical UniPulse 400 was tested for performance in accordance with the following standard:

- BS EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- BS EN 61000-3-2:2006+A2:2009 Harmonics
- BS EN 61000-3-2:2013 Flicker
- BS EN 61000-4-2:2009 Electrostatic Discharge
- BS EN 61000-4-2:2006+A2:2010 Radiated Immunity
- BS EN 61000-4-2:2012 Fast Burst Transients
- BS EN 61000-4-5:2006 Surge Transients
- BS EN 61000-4-6:2009 Conducted Immunity
- BS EN 61000-4-11:2004 Voltage Dips and Short Interruptions
- CISPR 11/BS EN 55011 Radiated Emissions
- CISPR 11/BS EN 55011 Conducted Emissions

Test results indicate that the Rigel Medical UniPulse 400 complies with the applicable standards.

Performance Testing – Bench

The Rigel Medical UniPulse 400 was tested for performance in accordance with its predetermined specifications.

The results of the performance testing show the Rigel Medical UniPulse 400 complies with these specifications.

Conclusion

A comparison of the predicate device and a review of the testing results shows that the Rigel Medical UniPulse 400 is substantially equivalent to the predicate device.