January 7, 2024

Shenzhen Lifetech Cardio Medical Electronics Co., Ltd.
Stephy Pan
Regulatory Affairs Director
1401, Building D1, Nanshan I Park
No.1001, Xueyuan Avenue, Taoyuan Street, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K232721
Trade/Device Name: Lifetech Cardio Temporary Pacemaker
Regulation Number: 21 CFR 870.3600
Regulation Name: External pacemaker pulse generator
Regulatory Class: Class II
Product Code: DTE
Dated: December 8, 2023
Received: December 8, 2023

Dear Stephy Pan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica L. Batista -S

Digitally signed by Jessica L. Batista -S
Date: 2024.01.07 18:58:05 -05'00'

for

Sara Royce
Assistant Director

Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OOffice 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232721

Device Name
Lifetech Cardio Temporary Pacemaker

Indications for Use *(Describe)*
The intended uses of Lifetech Cardio Temporary Pacemaker are
1. to provide temporary single chamber synchronous or asynchronous anti-brady pacing therapy, and
2. to test electrical performance of an implanted lead system, including pacing threshold, sensing sensitivity and impedance .
Lifetech Cardio Temporary Pacemaker is only intended to be operated 1. in a clinical setting, and 2. by trained professionals.

Indications for anti-brady pacing therapy may be based on symptomatic bradycardia conditions that:
1. results from an acute and reversible cause and will likely not require permanent pacing, and
2. causes symptoms and/or severe hemodynamic impairment and when permanent cardiac pacing is not immediately indicated or available.

Examples of specific indications for temporary pacing may include:
a) Sick sinus syndrome
b) Sinus bradycardia
c) Atrial and/or ventricular arrhythmias
d) Complete atrioventricular block
e) Asystole
f) Bradycardia accompanied by congestive heart failure
g) Patient support, management and evaluation before the implantation of implantable pacemaker
h) Support during the replacement of implantable pacemaker
i) Cardiac complications occurring during intervention or surgery
j) Support after the cardiac surgery
k) Acute myocardial infarction complicated with cardiac conduction block
l) High-rate burst pacing for the treatment of supraventricular tachyarrhythmias

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.

510(k) Summary

A. General Information

Date Prepared:	June 15th, 2023
510(k) Owner/Submitter:	Shenzhen Lifetech Cardio Medical Electronics Co., Ltd.
Address:	1401, Building D1, Nanshan i Park,No.1001, Xueyuan Avenue, Taoyuan Street, Nanshan District, Shenzhen, Guangdong, 518000, China
Contact:	Stephy Pan Regulatory Affairs Director
Telephone:	+86 755 23251894 +86 13632729557
E-mail:	panyuying@ltcardio.com
Proprietary Name:	Lifetech Cardio Temporary Pacemaker
Common Name:	External Pacemaker Pulse Generator
Device Classification:	Class II, 21 CFR 870.3600 External Pacemaker Pulse Generator
Product Code:	DTE
Regulation Medical Specialty	Cardiovascular
Model	8301,8201,8200,7101,7100

B. Predicate Device and Reference Device

Predicate Device

Trade Name	Lifetech Cardio Model 8301 Temporary Pacemaker
510(k) Number	K182839
Product Code	DTE
Manufacturer	Shenzhen Lifetech Cardio Medical Electronics Co.,Ltd

Reference Device

Trade Name	Medtronic Model 53401 External Pulse Generator
510(k) Number	K180873
Product Code	DTE
Manufacturer	Medtronic, Inc.

C. Device Description

The Lifetech Cardio Temporary Pacemaker (hereinafter called “TPM”) is a handheld device powered by two common size AA 1.5V Alkaline (LR6) batteries, which is intended for temporary single chamber anti-brady pacing therapy and implanted

system analysis. The TPM offers a complete set of pacing and sensing controls and supports either SSI (synchronous) or SOO (asynchronous) pacing modes. Its analysis features enable pacing threshold, sensing sensitivity and impedance measurement.

The accessories for connecting a pacing lead system to the TPM include:

- Patient Cable
- Analysis Cable

D. Intended Use/ Indications for Use

The intended uses of Lifetech Cardio Temporary Pacemaker are

1. to provide temporary single chamber synchronous or asynchronous anti-brady pacing therapy, and

2. to test electrical performance of an implanted lead system, including pacing threshold, sensing sensitivity and impedance (model 7101,7100 excluded).

Lifetech Cardio Temporary Pacemaker is only intended to be operated

1. in a clinical setting, and

2. by trained professionals.

Indications for anti-brady pacing therapy may be based on symptomatic bradycardia conditions that:

1. results from an acute and reversible cause and will likely not require permanent pacing, and

2. causes symptoms and/or severe hemodynamic impairment and when permanent cardiac pacing is not immediately indicated or available.

Examples of specific indications for temporary pacing may include:

a) Sick sinus syndrome
b) Sinus bradycardia
c) Atrial and/or ventricular arrhythmias
d) Complete atrioventricular block
e) Asystole
f) Bradycardia accompanied by congestive heart failure
g) Patient support, management and evaluation before the implantation of implantable pacemaker
h) Support during the replacement of implantable pacemaker
i) Cardiac complications occurring during intervention or surgery
j) Support after the cardiac surgery
k) Acute myocardial infarction complicated with cardiac conduction block
l) High-rate burst pacing for the treatment of supraventricular tachyarrhythmias

E. Comparison of Technological Characteristics with the Predicate

The new RAP (Rapid Atrial Pacing) feature of the subject device is indicated for the high-rate burst pacing for the treatment of supraventricular tachyarrhythmias, which is different from the predicate device. However, the difference does not alter the intended therapeutic use of the device nor do it affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use of providing temporary single chamber pacing therapy and testing electrical performance of an implanted lead system by generating the parameter-variable electric pulse and the conduction of pacing lead.

Device

The subject device has the same Physical Characteristics, Principles of Operation, Basic Pacing Parameters, Safety Features and Standards as the predicate device. The Functional Features are different from the predicate device due to the new feature of RAP (Rapid Atrial Pacing). However, the new feature of RAP has the same principles of operation with the basic pacing feature. It is concluded that the new RAP feature of the subject device does not raise new questions of safety and effectiveness and also does not change the technological characteristic of the device. Therefore, the subject device has the same technological characteristic as the predicate device.

F. Performance Tests

Lifetech Cardio has conducted a risk analysis and has performed the necessary Software and Bench testing (summarized below) in below to demonstrate that the design outputs of the modified device meet the design input requirements in relation to supporting the changes. Changes are verified and validated with the same verification and validation method as used in the previously cleared 510(k).

- Analysis Cable test
- Pacing Percentage Statistics test
- Rapid Atrial Pacing function test
- Software verification and validation

G. Conclusion

Based on the test data, the same intended use and technological characteristic, the modified Lifetech Cardio Temporary Pacemaker is substantially equivalent to the predicate device.