February 28, 2019

Shenzhen Lifetech Cardio Medical Electronics Co., Ltd.
Stephy Pan
Quality and Regulatory Affairs Manager
Rm 201, Bldg No.2, Huahan Sci-tech Industrial Park,
No.16 Jinniu West Rd
Shenzhen, CN 518000 Guangdong

Re: K182839
Trade/Device Name: Lifetech Cardio Model 8301 Temporary Pacemaker
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: Class III
Product Code: DTE
Dated: January 9, 2019
Received: January 17, 2019

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 (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,

Hetal B. Patel -S Digitally signed by Hetal B. Patel -S Date: 2019.02.28 09:41:05 -05'00' 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)*
K182839

Device Name
Lifetech Cardio Model 8301 Temporary Pacemaker

Indications for Use *(Describe)*
The intended uses of Lifetech Cardio Model 8301 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 Model 8301 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

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

A. General Information

Date Prepared:	September 25th, 2018
510(k) Owner/Submitter:	Shenzhen Lifetech Cardio Medical Electronics Co., Ltd.
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E-mail:	panyuying@lifetechmed.com
Proprietary Name:	Lifetech Cardio Model 8301 Temporary Pacemaker
Common Name:	External Pacemaker Pulse Generator
Device Classification:	Class II (special controls), 21 CFR 870.3600 External Pacemaker Pulse Generator
Product Code:	DTE
Regulation Medical Specialty	Cardiovascular

B. Predicate Device

Trade Name	Medtronic Model 5318 Temporary Pacemaker / Implant Tool
510(k) Number	K971474
Product Code	DTE
Manufacturer	Medtronic, Inc.

C. Device Description

Lifetech Cardio Model 8301 Temporary Pacemaker (hereinafter called “8301 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. 8301 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.

Patient Cable is an accessory provided along with 8301 TPM and is designed to connect a pacing lead system to 8301 TPM.

D. Intended Use/ Indications for Use

The intended uses of Lifetech Cardio Model 8301 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.

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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.

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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

E. Technological Characteristics

Intended use, technological characteristic and performance are substantially equivalent to the predicate devices referenced.

When compared to the predicate device, Lifetech Cardio Model 8301 Temporary Pacemaker presented in this submission has the same:

Intended Use
- Intended Use
- Anatomical Sites
- Target Population
- Indications for Use
- Contraindications

Technological Characteristic
- Accessory
- Physical Characteristics
- Principles of Operation

Performance
- Pacing Parameters
- Analysis Features
- Safety Features
- Standards

F. Summary of Testing

Design verification and validation was performed to demonstrate that Lifetech Cardio Model 8301 Temporary Pacemaker and its accessory meet established performance criteria to support substantial equivalence to the referenced predicate device.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Lifetech Cardio Model 8301 Temporary Pacemaker with associated cables as necessary for test. The system complies with the IEC 60601-1 and IEC 60601-2-31 standards for safety and the IEC 60601-1-2 of the standard for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Bench Testing
- Physical Characteristics
- Electrical Parameters and Features
- Cleaning Method Validation
- Hardware Reliability

- Environmental Requirements

G. Conclusion

Design verification and validation results demonstrate that Lifetech Cardio Model 8301 Temporary Pacemaker performs as intended when used in accordance with its labeling and is considered substantially equivalent to Medtronic Model 5318 Temporary Pacemaker / Implant Tool .