DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 25, 2016

Bio Trace Medical, Inc.
Laura Dietch
President and CEO
831 Bransten Rd, Suite L
San Carlos, California 94070

Re: K160260
Trade/Device Name: Tempo Temporary Pacing Lead
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: September 23, 2016
Received: September 26, 2016

Dear Laura Dietch:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160260

Device Name
Tempo Temporary Pacing Lead

Indications for Use *(Describe)*

The BioTrace Medical Tempo Temporary Pacing Lead is indicated for use in temporary intracardiac pacing for a maximum of seven (7) days and is designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.

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.

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510(k) SUMMARY for K160260

General Information:

Date of Summary Preparation:	October 20, 2016
Name and Address of Manufacturer:	BioTrace Medical, Inc. 831 Bransten Road, Suite L San Carlos, CA 94070
Contact Person:	Laura N. Dietch President and CEO
Device Trade Name:	Tempo® Temporary Pacing Lead
Common Name:	Temporary Lead
Regulation Number:	21 CFR 870.3680(a)
Regulation Name:	Temporary Pacemaker Electrode
Regulatory Class:	Class II
Classification Panel:	Cardiovascular
Product Code:	LDF

Performance Standards: No performance standards currently exist for these devices. However, BioTrace Medical has followed, in part, FDA's *Guidance for Industry: Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions (November 1, 2000).* Specifically, BioTrace Medical has considered the following sections of the aforementioned guidance document during the design verification and validation testing:

Bench Testing
- Bond Joint Strength
- Fatigue Resistance
- Corrosion Resistance

Electrical Safety Testing
Biocompatibility Testing
GLP Animal Studies
Clinical Study

Device Description: The BioTrace Medical Tempo Temporary Pacing Lead is designed for temporary transvenous intracardiac pacing. The lead provides access to the right ventricle via either the femoral vein, subclavian vein or the internal jugular vein approach and may be shaped near the distal end to facilitate delivery. It is a radiopaque, polymeric lead featuring a balloon, active fixation, bipolar electrodes and a soft tip.

Indications for Use: The BioTrace Medical Tempo Temporary Pacing Lead is indicated for use in temporary intracardiac pacing for a maximum of seven (7) days and is designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.

Predicate Device: BioTrace Medical cites the following as predicate and reference devices.

Predicate Device	Medtronic Temporary Transvenous Pacing Lead System (Model 6416)	K042190
Reference Devices	C.R. Bard Temporary Pacing Electrode Catheters	K800298

Technological Comparison:

For the purpose of demonstrating the substantial equivalence of the Tempo Temporary Pacing Lead in this 510(k), BioTrace Medical has selected the Medtronic Temporary Transvenous Pacing Lead System (Model 6416), #K042190. The Tempo Temporary Pacing Lead was assessed for substantial equivalence relative to the legally marketed predicate device with respect to intended use, indications for use, and technological characteristics as summarized below.

Design/Technological Characteristic	**BioTrace Medical (Subject Device, K160260)**	**Predicate Device (K042190)**
Indications for Use	The BioTrace Medical Tempo Temporary Pacing Lead is indicated for use in temporary intracardiac pacing for a maximum of seven (7) days and is designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.	The Medtronic Model 6416 Temporary, Transvenous Pacing Lead System features an active fixation, bipolar lead and a soft-tipped lubricated guide catheter. The system is designed for temporary intracardiac pacing and/or EGM recording. The system is disposable, for temporary single patient use, with contemplated implant duration of 7 days or less. The lead and accessories are supplied sterile. The lead is introduced transvenously using the guide catheter. Once within the appropriate chamber, the helical tip electrode of the lead is actively fixed into the endocardium. After lead placement the guide catheter is removed by sliding it over the lead's bifurcated connector.
Lead Type	Temporary, single-use	Temporary, single-use
Lead Introduction Method	By cutdown or by use of a percutaneous catheter introducer or needle cannula	By cutdown or by use of a percutaneous catheter introducer or needle cannula
Device Compatibility	Cannula or percutaneous introducer set to accommodate a 6F catheter	Cannula or percutaneous introducer set to accommodate a 6F catheter
Distal Configuration	Straight with fixation (stabilizers)	Straight with fixation (helix)
Balloon	Yes	No

Lead Type	Bipolar	Bipolar
Fixation	Yes	Yes
Number of Electrodes	Two (2)	Two (2)
Single-use only	Yes	Yes
Non-pyrogenic	Yes	Yes

Testing Summary: To demonstrate intended device performance, as well as to support the substantial equivalence of the subject Tempo Temporary Pacing Lead to the predicate device, the technological and performance characteristics were evaluated by completion of the following testing:

- Design Verification
  - Bond Joint Strength
  - Fatigue Resistance
  - Corrosion Resistance
  - Simulated Use
  - Electrical Resistance
- Electrical Safety Testing
- Packaging Validation
- Sterilization Validation
- Shelf Life Testing (Accelerated Aging)
- Biocompatibility
  - Cytotoxicity
  - Sensitization
  - Irritation Reactivity
  - Systemic Toxicity
  - Subchronic Toxicity
  - Genotoxicity
  - Implantation
  - Hemocompatibility
  - Hemolysis
  - Complement Activation
  - In Vivo Thrombogenicity
  - Pyrogenicity
- GLP Animal Testing
- Clinical Study:

  The Tempo® Study was a prospective, multicenter, non-randomized, single arm study to evaluate the safety and effectiveness of the Tempo® Temporary Pacing Lead in patients requiring temporary cardiac pacing for transcatheter aortic valve replacement, balloon aortic valvuloplasty or electrophysiology (EP) procedures. Twenty five (25) patients were enrolled in two centers. The device was evaluated for safety (freedom from pericardial effusion requiring intervention and/or echocardiographic evidence of tamponade) and technical feasibility (intracardiac

delivery and pace capture). Additional evaluations included pace capture thresholds (PCT), success of rapid pacing, and incidence of dislodgement or sustained ventricular arrhythmias (>30 seconds). Transthoracic echocardiograms were obtained at baseline and 24 hours after lead removal. Follow up was to 30 days.

The safety endpoint was met in all patients (100%) with no device-related adverse events. The technical feasibility endpoint was met in 23 patients (92%). No patient had a sustained ventricular arrhythmia or lead dislodgement. Average final procedural PCT was 0.7±0.5 mA. Rapid pacing was successful in all cases, with no loss of pace capture. In 5 patients the lead was successfully used post-procedure.

This first-in-human study demonstrates that the Tempo Lead is safe and effective for temporary cardiac pacing.

The results from these tests and studies demonstrate that the technological and performance characteristics of the subject Tempo Temporary Pacing Lead are adequate for its intended use and ensure the subject device can perform in a manner equivalent to devices currently on the market with the same intended use.

Conclusion: The data and information presented within this submission (including *in vitro* bench, *in vivo* animal testing and the clinical study) support a determination of substantial equivalence of the Tempo Temporary Pacing Lead to marketed temporary pacing leads.