



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 05, 2016

Tiger Medical Products
% Pamela Papineau
President
Delphi Medical Device Consulting, Inc
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K152947

Trade/Device Name: Disposable Temporary Pacing Cable
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: February 16, 2016
Received: February 19, 2016

Dear Pamela Papineau:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152947

Device Name

Disposable Temporary Pacing Cable

Indications for Use (Describe)

The PXT701 Disposable Temporary Pacing Cable is designed to connect a pacing system analyzer (PSA) or temporary pacemaker to a cardiac lead.

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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General Information

Owner's Name: Tiger Medical Products
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Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432
Telephone Number: (978) 772-3552
Fax Number: (978) 796-5460

Subject Device:
Trade Name: Disposable Temporary Pacing Cable
Common Name: Component to diagnostic or physiological monitoring devices
Product Code: DSA
FDA Regulation: 21 CFR 870.2900 – Cable, Transducer and Electrode, Patient (Including Connector)
Device Classification: Class II

Predicate Device:
Product Name: Safe Connect Disposable Surgical Cable
Common Name: Component to diagnostic or physiological monitoring devices
Product Code: DSA
FDA Regulation: 21 CFR 870.2900 – Cable, Transducer and Electrode, Patient (Including Connector)
Device Classification: Class II
Premarket Notification: K971968

Indications for Use

The PXT701 Disposable Pacing Cable is designed to connect a pacing system analyzer (PSA) or temporary pacemaker to a cardiac pacing lead.

Device Description:

The Disposable Temporary Pacing Cable is an electrical extension cable used to transmit signal from, or power or excitation signal to patient-connected electrodes. The cable is bipolar, with alligator clips at the end of the cable that will be attached to the patient leads, and a safety plug instrument connector at the other end that allows electrical connection to a pacing system analyzer or to an external pacing system (temporary pacemaker). The alligator clips are color coded (red = positive; black = negative). The cable is approximately 2.5 meters (8 feet) long, and is supplied sterile. The cable is a disposable, single-patient use device.

Substantial Equivalence

The Tiger Medical Products Disposable Temporary Pacing Cable is substantially equivalent to the Remington Medical, Inc. Safe Connect Surgical Cable (K971968). Substantial equivalence, which is summarized below, is based on indications for use and device physical and technological characteristics.

	Tiger Medical Products Disposable Temporary Pacing Cable (current submission)	Remington Medical, Inc. Disposable Surgical Cable (K971968)
Device Common/Usual Name	Component to diagnostic or physiological monitoring devices	Component to diagnostic or physiological monitoring devices
Device Class	Class II	Class II
Product Code / Regulation	DSA / 21 CFR 870.2900	DSA / 21 CFR 870.2900
Regulation Name	Cable, Transducer and Electrode, Patient (Including Connector)	Cable, Transducer and Electrode, Patient (Including Connector)
Prescription Use	Rx Only	Rx Only
Intended Use	For temporary connection of a pacing system analyser (PSA) or temporary pace maker to a cardiac pacing lead.	For temporary connection of a pacing system analyser (PSA) or temporary pace maker to a cardiac pacing lead.
Indications for Use Statement (ref. Proposed and Predicate Device Labeling; Appendix B)	To connect a pacing system analyser (PSA) or temporary pace maker to a cardiac pacing lead.	To act as a conduit for the electrical signal generated from a Pacing System Analyzer (PSA) or External pacing Generator (EPG) to a permanent pacemaker lead or epicardial wire.
Overall Cable Length	2.5 meters / 8 feet	2.5 meters / 8 feet
Lead Wire Cable Connectors	Alligator clips with color coded boots (black = negative; red = positive)	Alligator clips with color coded boots (black = negative; red = positive)
Instrument Connector	“safe-connect” style	“safe-connect” style
Wire Type	22-gauge metallic wire with plastic insulation	22-gauge metallic wire with plastic insulation
Lead Compatibility	Single-Chamber Unipolar Leads; Single-Chamber Bipolar Leads; Dual Chamber Unipolar Leads; Dual Chamber Bipolar Leads	Single-Chamber Unipolar Leads; Single-Chamber Bipolar Leads; Dual Chamber Unipolar Leads; Dual Chamber Bipolar Leads
Performance Testing per ANSI/AAMI EC53?	Yes	Yes
Sterile Device?	Yes	Yes
Sterilization Type	Ethylene Oxide	Ethylene Oxide
EO Sterilization Residuals	Per ISO 10993-7	Per ISO 10993-7
Disposable / Reusable	Disposable	Disposable
Shelf Life	5 years	3 years

Performance Testing:

Performance testing for the Tiger Medical Products Disposable Temporary Pacing Cable consists of physical integrity and electrical resistance in accordance with ANSI/AAMI EC53:2013 (dielectric withstand voltage, defibrillation withstand test, cable and leadwire noise, sink current, connector tensile strength, connector flex life testing, number of connector mate/unmate cycles, contact resistance, connector retention force and patient leadwire resistance). The Tiger Medical Products Disposable Temporary Pacing Cable has met all applicable acceptance criteria as defined in ANSI/AAMI EC53:2013 with the exception of cable noise. The test results for cable noise were equivalent to the results of the same testing performed on the predicate device.

Conclusion:

The Tiger Medical Products Disposable Temporary Pacing Cable has been demonstrated to be substantially equivalent to the predicate device.