



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 15, 2015

Edwards Lifesciences, LLC
Deana Boushell
Sr. Principal Project Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K152633

Trade/Device Name: Chandler Transluminal Bipolar Pacing Probe, Flextip Transluminal Bipolar Pacing Probe
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: September 14, 2015
Received: September 15, 2015

Dear Deana Boushell:

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", is written over a faint, light-colored FDA logo watermark.

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)

K152633

Device Name

Bipolar Transluminal Pacing Probes

Indications for Use (Describe)

The Chandler Transluminal V-Pacing Probe is indicated for temporary emergency ventricular pacing when used with a Swan-Ganz Paceport or A-V Paceport catheter, and can be inserted with or without the aid of fluoroscopy. The probe can also be used for intraventricular ECG detection (during placement).

The Flex-Tip Transluminal A-Pacing Probe is indicated for temporary emergency atrial pacing or sequential A-V pacing when used with a Swan-Ganz A-V Paceport catheter, and can be inserted with or without the aid of fluoroscopy. The probe can also be used for intraatrial ECG detection (during placement).

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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SECTION 5 – 510(k) SUMMARY

Chandler™ Transluminal V-Pacing Probe and Flex-Tip™ Transluminal A-Pacing Probe	
510(k) Submitter	Edwards Lifesciences, LLC
Establishment Registration Number	2015691
Address	One Edwards Way Irvine, CA 92614 Phone: 949-250-2500
Contact Person	Deana M. Boushell RAC Senior Principal Project Manager, Regulatory Affairs Direct Line: 949-250-4472 email: deana_boushell@edwards.com FAX: 949-809-2967
Date Prepared	September 14, 2015
Trade Names	Chandler Transluminal V-Pacing Probe Flex-Tip Transluminal A-Pacing Probe
Common Name	Pacing Probe
Classification Name	Electrode, Pacemaker, Temporary 21 CFR 870.3680(a), Product Code LDF
Regulation Class/Product Code	Class II LDF
Predicate Device(s)	K813521 Transluminal™ BiPolar Pacing Probe (cleared March 15, 1982)
Device Description	The Chandler Transluminal V-Pacing Probe and the Flex-Tip Transluminal A-Pacing Probe are 2.4F probes indicated for temporary emergency pacing of either the ventricle or atrium.
Models	Chandler Transluminal V-Pacing Probe Model: D98100 Flex-Tip Transluminal A-Pacing Probe Model: D98500

Device Characteristics	
Indications for Use/Intended Use	<p>The Chandler Transluminal V-Pacing Probe is indicated for temporary emergency ventricular pacing when used with a Swan-Ganz Pacerport or A-V Pacerport catheter, and can be inserted with or without the aid of fluoroscopy. The probe can also be used for intraventricular ECG detection (during placement).</p> <p>The Flex-Tip Transluminal A-Pacing Probe is indicated for temporary emergency atrial pacing or sequential A-V pacing when used with a Swan-Ganz A-V Pacerport catheter, and can be inserted with or without the aid of fluoroscopy. The probe can also be used for intraatrial ECG detection (during placement).</p>
Environment of Use	<p>The system is intended for use by a trained clinician in a hospital or other appropriate clinical setting.</p>
Device Description	<p>The Chandler Transluminal V-Pacing probe is a 2.4F pacing probe with a straight distal electrode tip for emergency temporary ventricular pacing when connected to an external pulse generator.</p> <p>The Flex-Tip Transluminal A-Pacing probe is a 2.4F pacing probe with a 'J' tip distal electrode for emergency temporary atrial or A-V sequential pacing when connected to an external pulse generator.</p>
Key Performance Specifications/ Characteristics of the Device	<p>The Chandler Transluminal V-Pacing probe and the Flex-Tip Transluminal A-Pacing probe have a total usable length of 135 cm and a usable length of 15 cm in either the ventricle or atrium. The devices incorporate an electrode pair that is comprised of stainless steel with adequate surface area to depolarize the cardiac tissue.</p>
Comparative Analysis	<p>Material biocompatibility testing in compliance with applicable ISO 10993 requirements, and performance testing was conducted to compare the subject devices to the predicate device. The results of the testing indicate that the fundamental scientific technology of the proposed devices remain unchanged from the legally marketed predicate device.</p> <p>The proposed change to the Chandler Transluminal V-Pacing probe and the Flex-Tip Transluminal A-Pacing probe has been shown to be safe, effective, and substantially equivalent to the predicate device (K813521 Transluminal BiPolar Pacing Probe) for its intended use.</p>
Functional/ Safety Testing	<p>The Chandler Transluminal V-Pacing probe and the Flex-Tip Transluminal A-Pacing probe have successfully passed functional-performance testing and biocompatibility testing, in accordance with applicable consensus standards.</p>
Conclusion	<p>The Chandler Transluminal V-Pacing Probe and the Flex-Tip Transluminal A-Pacing Probe have been shown to be substantially equivalent to the predicate Transluminal BiPolar Pacing Probe and safe and effective for their intended use.</p>