K110133

CREGANNA
TACTX MEDICAL

JUN 10 2011

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General Information:

Submitter:	Creganna Tactx Medical, Inc. 1353 Dell Avenue Campbell, Ca 95008 Ph: (408) 364-7100 Fax: (408) 871-2425
Contact Person:	Dennis Wong Director of Quality
Date Prepared:	January 17, 2011
Device Trade name(s):	EMPIRA Rx PTCA Dilatation Catheter and EMPIRA NC Rx PTCA Dilatation Catheter
Device Common name:	PTCA Catheter
Class:	II
Classification Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter (21 CFR 870.5100)
Product Code:	LOX

Predicate Device(s):

Device Name	Reference(s)
EMPIRA Rx PTCA Dilatation Catheter	
Standard PTCA Catheter	21 CFR 870.5100
Cordis Fire Star	P880003
Boston Scientific's Maverick^2 Monorail	P860019
EMPIRA NC Rx PTCA Dilatation Catheter	
Standard PTCA Catheter	21 CFR 870.5100
Cordis Dura Star	P880003
Boston Scientific's Quantum Maverick Monorail	P860019

Note: Recently, PTCA Catheters were reclassified by the agency from Class III to Class II with Special Controls per FDA Guidance Document – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters issued September 8, 2010.

Intended Use:

The EMPIRA Rx PTCA Catheter and EMPIRA NC Rx PTCA Dilatation Catheter are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The EMPIRA NC Rx PTCA Dilatation Catheter is also indicated for post-delivery expansion of balloon expandable stents.

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Device Description:

The EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters, hereafter referred to as the EMPIRA Catheter, are similar in design. The catheters differ in available configurations (diameter versus balloon working length). The EMPIRA Catheter is a sterile, single-use rapid exchange catheter with a nylon-blend balloon near the distal tip. The distal section of the catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon and the inner lumen permits the use of a guide wire ($\leq$ 0.014 in. / 0.36 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The proximal section of the catheter is a single lumen stainless steel PTFE coated hypotube with a single luer port for the inflation / deflation of the balloon. The balloon is designed to provide an inflatable segment of specified diameter and length at recommended pressures. The balloon is folded to achieve a low crossing profile and is connected to a tapered, soft tip. The tapered tip facilitates advancement of the catheter to and through the stenosis. A hydrophilic coating is applied from the distal tip to the guide wire port and over the balloon for increased lubricity. All models have two radiopaque marker bands that aid in the placement of the catheter's balloon segment under fluoroscopy. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed in the lumen to maintain patency. The proximal end of the catheter is comprised of a hypotube connected to a plastic hub. The hub can be connected to a standard inflation device and is used to inflate/deflate the balloon. A needle with a luer port is included for flushing the distal lumen prior to the insertion of a guide wire.

The EMPIRA Catheter is compatible with standard 0.014" coronary guide wires and 5F guiding catheters. The catheter length is approximately 139 cm. The EMPIRA and EMPIRA NC Rx PTCA Catheters are offered in diameters of 1.5- 4.0 mm and 2.0-4.0, respectively. The working lengths of the treatment balloon are offered in lengths from 6.0 to 30mm. The EMPIRA and EMPIRA NC Rx PTCA Balloon Dilatation Catheter product family consists of multiple sizes.

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Device Comparison:

Below is a comparison of the EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters with Standard PTCA Catheter as defined by 21 CFR 870.5100:

1. Like Standard PTCA Catheters, the EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters operate on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end of the catheter.
2. Like Standard PTCA Catheters, the EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters have a double-lumen coaxial shaft.
3. Like Standard PTCA Catheters, the balloons on the EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters are constructed from a polymer (nylon) and have nominal rated pressures of 8 and 14atm, respectively.
4. Like Standard PTCA Catheters, the balloon on the EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters are available in different diameters and lengths.
5. Like Standard PTCA Catheters, the EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters have radiopaque marker bands to allow for visualization under fluoroscopy.
6. Like Standard PTCA Catheters, the EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters have the same intended use – indicated for the balloon dilatation of stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. In addition, the EMPIRA NC Rx PTCA Balloon Dilatation Catheter is also indicated for the post-delivery expansion of balloon expandable stents.

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The table below also provides a comparison to other legally marketed devices.

Item		Pre-Dilatation Catheters			Post-Dilatation Catheters		
		EMPIRA	Fire Star	Maverick Monorail	EMPIRA NC	Dura Star	Quantum Maverick Monorail
Manufacturer		Creganna-TACTX Medical	Cordis – Johnson & Johnson	Boston Scientific	Creganna-TACTX Medical	Cordis – Johnson & Johnson	Boston Scientific
Submission Reference		Current Submission	P880003	P860019	Current Submission	P880003	P860019
Intended Use		Note 1	Same	Same	Note 1	Same	Same
Principle of Operation		Note 2	Same	Same	Note 2	Same	Same
Catheter Characteristics	**Configuration**	Rapid Exchange	Same	Same	Rapid Exchange	Same	Same
	Effective Length (cm)	139	145	143	139	145	143
Balloon Characteristics	**Balloon Lengths (mm)**	6.0-30mm	10-30mm	9.0-30mm	6.0-30mm	10-30mm	8.0-30mm
	Balloon Diameters (mm)	1.5 – 4.0mm	1.5 – 3.5mm	1.5-4.0mm	2.0 - 4.0mm	2.25 – 4.0mm	2.0-5.0mm
	Nominal Pressure (atm)	8	8	6	14	14	12
	Rated Burst Pressure (atm)	14	14	12-14	20	20	16-18
Other Characteristics	**Guidewire compatibility**	≤0.014in	Same	Same	≤0.014in	Same	same
	Sterilization Method	Ethylene Oxide	Same	Same	Ethylene Oxide	Same	same
	Single-Use?	Yes	Same	Same	Same	Same	Same
	Hydrophilic Coating	Yes	Yes	Yes	Yes	Yes	Yes

Note 1: Indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Also, indicated for post-delivery stent expansion.

Note 2: Operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end.

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Summary of Non-Clinical Testing:

The EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters were tested in accordance of FDA Guidance Document – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters. The following testing was completed:

Test	Method	Results
Cytotoxicity	In accordance with ISO 10993	PASS
Hemolysis		
Platelet and Leukocyte Counts		
Partial Thromboplastin Time (PTT)		
Complement Activation		
Thromboresistance		
Bacterial Mutagenicity Test		
Intracutaneous Reactivity		
Materials Mediated Pyrogen		
Sensitization		
Acute Systemic Toxicity		
USP Physico-chemical		
Dimensional Verification	In accordance with applicable requirements of FDA Guidance Document - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters	PASS
Balloon Preparation, Deployment and Retraction		
Balloon Rated Burst Pressure		
Balloon Fatigue		
Balloon Compliance (diameter vs. Pressure)		
Balloon Inflation and Deflation Time		
Catheter Bond Strength(s)		
Tip Pull		
Flexibility and Kink		
Torque Strength		
Radiopacity		
Coating Integrity		
Particulate Evaluation		
Catheter Body Burst Pressure		
*Catheter Body Burst Pressure (In-Stent)		
*Balloon Rated Burst Pressure (In-Stent)		
*Balloon Fatigue (repeat balloon inflations; In-stent)		
Packaging Integrity Testing	In accordance with ISO 11607-1 and ISO 11607-2	PASS
Sterilization	In accordance with ISO 11135-1 and ISO 10993-7	PASS

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Test	Method	Results
Shelf Life	In accordance with applicable requirements of FDA Guidance Document - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters	PASS
Animal Study	Comparative testing to currently legally marketed devices in compliance with 21 CFR 58 - GLP	PASS

*This testing is not applicable to the EMPIRA Rx PTCA Dilatation Catheter because it is not intended for use In Stents.

Conclusion:

The EMPIRA and EMPIRA NC Rx PTCA Catheters are substantially equivalent to a Standard PTCA Catheter as defined in 21 CFR 870.5100 and other legally marketed devices with respect to intended use, principle of operation, technological characteristics and safety features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 10 2011

Creganna Tactx Medical, Inc.
c/o Mr. Dennis Wong
Director of Quality
1353 Dell Avenue
Campbell, CA 95008

Re: K110133
Trade/Device Name: EMPIRA™ Rx PTCA Dilatation Catheter
EMPIRA™ NC Rx PTCA Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: May 23, 2011
Received: May 24, 2011

Dear Mr. Wong:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K110133

Device Name: EMPIRA and EMPIRA NC Rx PTCA Dilatation Catheters

Indications for Use:

"The EMPIRA Rx PTCA Catheter and EMPIRA NC Rx PTCA Dilatation Catheter are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The EMPIRA NC Rx PTCA Dilatation Catheter is also indicated for post-delivery expansion of balloon expandable stents."

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110133