DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 14, 2016

Nipro Medical Corporation
Ms. Jessica Oswald-McLeod
Director of Quality Assurance and Regulatory Affairs
3150 NW 107th Ave.
Doral, FL 33172

Re: K151141
Trade/Device Name: Cronus HP - High Pressure Peripheral Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II
Product Code: LIT
Dated: December 14, 2015
Received: December 18, 2015

Dear Ms. Oswald-McLeod:

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" (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 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,

Kenneth J. Cavanaugh -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K151141

Device Name
Cronus HP - High Pressure Peripheral Balloon Catheter

Indications for Use *(Describe)*

The Cronus HP - High Pressure Peripheral Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty in the following vessel areas:
- Femoral arteries
- Popliteal arteries
- Iliac arteries
- Renal arteries
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

These catheters are not intended for use in coronary arteries or the neurovasculature.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: Cronus HP - High Pressure Peripheral Balloon Catheter

Applicant: Nipro Medical Corporation
3150 NW 107th Ave.
Miami FL 33172
Tel: 305-599-7174
Establishment Reg.: 1056186

Contact Person: Jessica Oswald-McLeod
Director, Quality Assurance & Regulatory Affairs

Date of summary preparation: January 12, 2016

Trade Name: Cronus HP - High Pressure Peripheral Balloon Catheter
Common Name: PTA Balloon Catheter
Classification Name: catheter, angioplasty, peripheral, transluminal
Regulation Number: 870.1250
Panel: Cardiovascular
Product Code: LIT

Legally marketed substantial equivalent device:

Primary Predicate: Covidien Evercross 0.035 OTW PTA Dilatation Catheter: K110319
Reference Device: Bard Conquest PTA Balloon Dilatation Catheter: K014212

Description of device:

The Cronus HP - High Pressure Peripheral Balloon Catheter is intended for PTA (Percutaneous Transluminal Angioplasty) procedures. It is an over the wire (OTW) 0.035" dual lumen catheter with a distally mounted semi- compliant inflatable balloon and a flush cut tip. The catheter manifold includes two lumens. A y-connector adaptation is located at the proximal part of the catheter and provides access to the two different lumens. The lumen marked "GW" is the central lumen of the catheter which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum outer diameter of 0.035 inches. The lumen, marked "BALLOON" is used to inflate and deflate the dilatation balloon with a solution of contrast medium and saline. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The balloon segment expands to a known diameter at a specific inflation pressure.
Cronus HP is sterilized using ethylene oxide gas and satisfies a minimum Sterility Assurance Level (S.A.L.) of 10^{-6}. Shelf-life is determined to be 2 years.

The device is available in multiple configurations ranging in sizes of balloon diameter 4-10mm, balloon lengths 20-60mm, and catheter lengths of 45 and 80cm

Indications for Use:

The Cronus HP- High Pressure Peripheral Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty in the following vessel areas: Femoral arteries, popliteal arteries, iliac arteries, renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. These catheters are not intended for use in the coronary arteries or the neourovasculature.

Comparison of technological characteristics:

The Cronus HP- High Pressure Peripheral Balloon Catheter is substantially equivalent to the predicate device in the following technological characteristics:

Characteristic	**Cronus HP- High Pressure Peripheral Balloon Catheter**	**Evercross**	**Conquest**
Physical characteristics	Components: • Balloon & Proximal shaft • Distal shaft • Soft tip • Hub with Luer lock connector • Markers • Strain relief / anti-kinking protector	Same	Same
Operational mode	Mechanical - inserted through an artery and guided to a location where the vessel has narrowed. Once the catheter is in place, contrast material will be injected and an angiogram or x-rays will be taken of the blocked vessel to help identify the site of the blockage. There, the balloon is inflated and deflated. In this process, the balloon expands the vein or	Same	Same

Characteristic	Cronus HP- High Pressure Peripheral Balloon Catheter	Evercross	Conquest
	artery wall, increasing blood flow		
Basic Scientific Technology	over the wire (OTW) 0.035" dual lumen balloon catheter	Same	Same
Intended Use	Intended for PTA (Percutaneous Transluminal Angioplasty). The catheter is used for the dilatation of stenosis in the peripheral vessel system and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulas.	Same	Same

Table 4: Technological Characteristics

Non-clinical tests submitted:

The following tests were conducted and passed on the Cronus HP - High Pressure Peripheral Balloon Catheter:

Biocompatibility and Chemical Characterization testing:

a) Bacterial endotoxin test (LAL test)
b) Bioburden test
c) Sterility test of BI
d) Sterility test of product
e) Cytotoxicity Study Using the ISO Elution Method
f) ASTM Hemolysis Study
g) ISO Systemic Toxicity Study in Mice
h) ISO Intracutaneus study in rabbits
i) ISO Guinea Pig Maximization Sensitization Test
j) USP Rabbit pyrogen study, material mediated
k) C3a Complement Activation Assay
l) SC5b-9 Complement Activation assay
m) ASTM Partial Thromboplastin Time

n) In vivo thromboresistance study in the dog, jugular vein

Bench Testing:

a) Packaging burst: the packaging integrity and its effectiveness over time were determined.
b) Guidewire compatibility: the ability of the guidewire to be slighted into the device and specifically within the guidewire lumen freely without resistance or without destroying the lumen was evaluated.
c) Visual verification: the ability of the catheter to conform to the product specifications in respect to surface defects and contamination that would make the catheter unsuitable for its intended use was evaluated. In general, the entire device was visually inspected for evidence of macroscopic damage.
d) Dimensional verification: the catheter dimensions were evaluated, in order to verify the design specifications and to evaluate the dimensional compatibility between the balloon catheter and the recommended accessory devices listed in the product IFU.
e) Profiles (Crossing, entry): the maximum diameter along sections of the catheter was measured in order to evaluate the dimensional compatibility between the balloon catheter and the vasculature, including the lesion to be treated.
f) Introducer sheath compatibility: the compatibility between the folded balloon and the recommended sheath listed in the product label was inspected.
g) Trackability: the ability of the balloon catheter to advance through the vessel to the target lesion using the recommended accessories was evaluated.
h) Pushability: the ability of the balloon catheter to be pushed or positioned by an operator without undesirable bending or buckling was evaluated. The samples were forwarded manually into the path until they reached to its end point.
i) Balloon flexibility three points: the bending flexibility of the balloon section, as a factor in its ability to track through the vascular anatomy and to conform to the natural curves of the vessel was characterized.
j) Balloon Inflation time at RBP: the time required to inflate the balloon to the maximum recommended inflation pressure was measured. This test provides information that might be clinically useful for treatment planning (e.g. potential occlusion time).
k) Balloon deflation time from RBP: the time required to deflate the balloon from the maximum allowed inflation pressure (RBP) was determined. This test provides information that might be clinically useful for treatment planning (e.g. potential occlusion time).
l) Deflated balloon retract through sheath: the required force to retract the rewrapped balloon through the artery and the sheath was determined. The test

evaluates and characterizes the rewrapping ability of the balloon under simulated use conditions.

m) Balloon diameter at nominal pressure: the inflated balloon diameter when is inflated at defined as nominal pressure was measured.
n) Balloon compliance: This test is conducted in order to quantify the balloon diameter as a function of the balloon inflation pressure.
o) Balloon fatigue test for freedom from leakage and damage on inflation: Evaluate the ability of the balloon to withstand repeated inflation cycles up to RBP.
p) Maximum balloon Inflation pressure: the highest pressure applied to the balloon before burst was determined. The average burst pressure (ABP) for the balloon was measured.
q) Balloon burst mode: the balloon geometrical failure mode after the balloon burst procedure.
r) RBP study: The Rated Burst Pressure (RBP) was verified according to the respective specifications. According to the burst test results of the balloon, the defined RBP of the product (26bar) is verified.
s) Bond strength: the bond strength of the joints and/or fixed connections of the balloon catheter was determined.
t) Tensile strength of tubing: Determination of the tubing tensile strength of the materials used in the balloon catheter.
u) Radiopacity: the ability of the balloon to be visualized when the catheter is inserted into the body by the use of fluoroscopy was determined. The radiopacity has been performed according to ASTM F640-12 standard.
v) Corrosion: The balloon catheter is composed of plastic tubings. This type of material cannot be corroded as it is not a metallic material.
w) bubble test and the seal strength test performed to the packaging: Seal strength testing was performed according to ASTM F88/F88-09 and the gross leak detection testing (bubble test) in accordance to ASTM 2096-11.
x) torque strength test and the Flex kink test: ensures the device can withstand forces that are typical of clinical use without device failure or vessel damage

Clinical tests:

This submission does not warrant any clinical testing, therefore no clinical testing performed for or provided in this submission.

Conclusions drawn from non-clinical tests:

The results of the performance testing and the comparison of technological characteristics with the predicate devices demonstrate that the Cronus HP- High Pressure Peripheral Balloon Catheter has an equivalent performance compared to the predicate devices and it is substantially equivalent for its intended use.