October 24, 2019

Nipro Medical Corporation
Ms. Jessica Oswald-Mcleon
Director, QARA
3150 NW 107th Ave.
Doral, Florida 33172

Re: K190037
Trade/Device Name: Cronus HP PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 20, 2019
Received: September 24, 2019

Dear Ms. Oswald-Mcleon:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190037

Device Name
Cronus HP PTA Balloon Catheter

Indications for Use *(Describe)*

The Cronus HP PTA 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)

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: Cronus™ HP PTA Balloon Catheter

807.92(a)(1)

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 4, 2019

807.92(a)(2)

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

807.92(a)(3)

Legally marketed substantial equivalent device:
Cronus HP – High Pressure Peripheral Balloon Catheter (K151141)

807.92(a)(4)

Description of device:
The Cronus™ HP PTA 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.
The Cronus™ HP PTA Balloon Catheter 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 4 years.

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

807.92(a)(5)

Indications for Use:

The Cronus™ HP PTA 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.

807.92(a)(6)

Comparison of technological characteristics:

The Cronus™ HP PTA Balloon Catheter is substantially equivalent to the predicate device in the following technological characteristics:

Table 5A: Technological Characteristics

Characteristic	Subject device Cronus HP	Predicate device Cronus HP (K151141)
Physical characteristics	Components: • Balloon & Proximal shaft • Distal shaft • Soft tip • Hub with Luer lock connector • Markers • Strain relief /anti-kinking protector • Refolding tool	Components are the same, minus the refolding tool which was not available on the predicate
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	Same

Characteristic	Subject device Cronus HP	Predicate device Cronus HP (K151141)
	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 artery wall, increasing blood flow	
Basic Scientific Technology	Over the wire (OTW) 0.035" dual lumen balloon catheter	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

807.92(b)(1)

Non-clinical tests:

The following tests were conducted successfully on the subject device

a) Bacterial endotoxin test (LAL test)*
b) Bioburden test
c) Sterility test of BI
d) Sterility test of product*
e) Biocompatibility and Chemical Characterization testing
    - 1. Cytotoxicity test
    - 2. Sensitization testing
    - 3. Intracutaneous reactivity testing
    - 4. Acute system toxicity
    - 5. Hemolysis test
    - 6. Complement activation testing
    - 7. PTT, P&L and SEM imaging for thrombogenicity

a) Bench Testing:

1. Packaging burst*: the packaging integrity and its effectiveness over time were determined.
2. Packaging bubble test*: Determination of the ability of packaging to withstand internal pressurization
3. Seal strength test*: Determination of packaging integrity.
4. 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.
5. Simulated use*: this test was conducted in order to demonstrate that the balloon catheter can be safely and reliably prepared, deployed, and retracted using the recommended techniques, accessory devices, and instructions of use, without damage the device.
6. Balloon inflation time*: 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).
7. Balloon deflation time*: 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).
8. Balloon compliance*: This test was conducted in order to determine the relation of balloon diameter to balloon pressure, which guides selection of catheter size to fit the target vasculature site.
9. Balloon fatigue test*: Evaluation of the ability of the balloon to withstand repeated inflation cycles up to RBP.
10. Balloon Rated Burst Pressure*: The highest pressure applied to the balloon before burst was determined. The failure mode was recorded and based on the obtained values the average burst pressure (ABP) and the Rated Burst Pressure (RBP) for the balloon were calculated.
11. Catheter bond strength / Tip pull test*: the bond strength of the joints and connections of the balloon catheter was determined.
12. Flexibility and Kink test*: the objective of this test was to evaluate the kink radii and to demonstrate that the device didn't kink at a bend radius that is appropriate for the intended anatomy
13. Torque strength test*: ability to withstand torsional forces that are typical of clinical use and could lead to device failure of vessel damage

14. 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.

* The tests with the asterisk were performed at zero time and also after accelerated aging treatment simulating 4 years of natural storage.

807.92(b)(2)

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

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:
The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the Cronus™ HP PTA Balloon Catheter is substantially equivalent to the predicate device.