September 6, 2018

Contego Medical, LLC
℅ Debra Cogan
Regulatory Consultant
QRAC, LLC
14906 Conway Avenue
San Jose, California 95124

Re: K181128
Trade/Device Name: Paladin Carotid Post-Dilation Balloon System with Integrated Embolic Protection
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, NTE
Dated: August 7, 2018
Received: August 9, 2018

Dear Debra Cogan:

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/pmncfmr 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Finn E. Donaldson - S

for

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

510(k) Number *(if known)*
K181128

Device Name
Paladin® Carotid Post-Dilation Balloon System with Integrated Embolic Protection

Indications for Use *(Describe)*
The Paladin System with Integrated Embolic Protection (IEP) is indicated for Percutaneous Transluminal Angioplasty (PTA) in the carotid arteries with capture and removal of embolic material. This device is also indicated for post-dilation of self-expanding stents in the carotid arteries with capture and removal of embolic material. The diameter of the arterial site for filter deployment should be no more than 7.0 mm. The Paladin System with IEP should always be used in conjunction with an available embolic protection device.

Type of Use *(Select one or both, as applicable)*
- [X] 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 [per 21 CFR 807.92]**

**Date Prepared:** April 27, 2018  
**Applicant:** Contego Medical, LLC  
3921 Sunset Ridge Rd., Suite 102  
Raleigh, NC 27607  
**Contact Person:** Debra Cogan  
Regulatory Affairs Consultant to  
Contego Medical, LLC  
Phone: (408) 515-0820  
Fax: (408) 273-6047  
dcogan@contegomedical.com

**Proprietary Name:** Paladin Carotid Post-Dilation Balloon System with Integrated Embolic Protection  
**Common Name:** Carotid Post-Dilation Balloon System with Integrated Embolic Protection  
**Device Classification:** Class II  
**Regulation Number:** 870.1250  
**Classification Name:** Percutaneous Catheter

**Product Code:** LIT, NTE  
**Device Description:** The Paladin System is a sterile, single use, rapid exchange (RX) PTA catheter with a nitinol-based filter between the PTA balloon and the distal tip of the catheter. The balloon has radiopaque markers to aid in accurate positioning under fluoroscopic guidance. The dilation balloon is designed to inflate to a known diameter and length at a specific inflation pressure. Paladin has balloon diameters Ø of 5.0 mm and 5.5 mm and balloon lengths of 20 mm and 30 mm.

The embolic protection filter is composed of a nitinol braid chassis with an overlying polyurethane membrane with radiopaque markers on either end and radiopaque markers on the filter. The catheter has a guidewire lumen, an inflation/deflation lumen, and a filter activation wire lumen. The guidewire lumen permits the passage of a guidewire to facilitate advancement of the catheter to and through the stenosis to be dilated. The proximal end of the catheter has a handle that controls activation.

The filter is identical across all sizes of balloons and can be expanded to a maximum diameter of 7 mm.

The Paladin System is designed to be introduced through a 6 French vascular sheath.
**Indications for Use:**
The Paladin System with Integrated Embolic Protection (IEP), is indicated for Percutaneous Transluminal Angioplasty (PTA) in the carotid arteries with capture and removal of embolic material. This device is also indicated for post-dilation of self-expanding stents in the carotid arteries with capture and removal of embolic material. The diameter of the arterial site for filter deployment should be no more than 7.0 mm. The Paladin System with IEP should always be used in conjunction with an available embolic protection device.

**Predicate Device(s):**
Boston Scientific Corp. Sterling Monorail Balloon Dilatation Catheter (K141150) - Primary predicate
Abbott Vascular RX ACCUNET Embolic Protection System (K153086)

**Comparison of Technological Characteristics**
Paladin has the same intended use as the predicate devices. The materials, design, and performance characteristics are similar. Balloon lengths and diameters are within the same range as the Sterling Monorail Balloon Dilatation Catheter. The filter element is intended to capture and remove embolic material while performing angioplasty and stenting procedures in the carotid arteries, which is the same as the RX ACCUNET Embolic Protection System. All devices are provided sterile, for single use only.

**Summary of Non-Clinical Data**
*Design Verification in-vitro testing:*
The following in-vitro bench tests were completed on the Paladin System in accordance with the requirements of Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010, and Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions, February 15, 2008, which verify that it meets the required performance specifications.

- Dimensional Verification
- Simulated Use
- Torque Response
- Balloon Rated Burst Pressure / Balloon Compliance
- Balloon Fatigue
- Inflation / Deflation time
- Catheter Bond Strength / Tip Tensile Strength
- Flexibility and Kink Testing
- Torque Strength
- Embolic Capture Efficiency and Retrieval Ability
- Stent Compatibility (the Paladin System was tested with the Cordis Precise Stent)
- Filter Capacity
- Resistance to Filter Rupture
- Flow Characteristics
- Balloon Rated Burst Pressure (in-stent)
- Balloon Fatigue (in-stent)
- Shelf Life
Biocompatibility Testing:
Biocompatibility testing for the Paladin System has been completed in accordance with the recommendations of Guidance for Industry and FDA Staff - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Issued June 16, 2016, for an external communicating device with limited exposure (i.e. whose contact with circulating blood is ≤ 24 hours).

Animal Testing:
Two animal studies were conducted in the swine model. The first was an acute study in one animal which assessed the ability to deploy the Paladin device through a pre-deployed stent. A second GLP study involved 12 animals treated with the Paladin platform through deployed stents. Animals were survived to 30 days and six months to assess histological safety. Both studies found the device to be well tolerated and safe based on local and dependent tissue response in the healthy swine model.

Summary of Clinical Data:
A Multi-Center Study to Evaluate Acute Safety and Clinical Performance of the Paladin System was conducted at five centers in Germany to assess the safety and clinical performance of the device in adults requiring percutaneous intervention of an asymptomatic (> 70%) or symptomatic (>50%) internal carotid artery stenosis. A total of 106 subjects were followed through 30 days to evaluate safety, device performance and clinical endpoints. A primary embolic protection device was used distal to and in conjunction with the Paladin System for this study. Patient demographics for age, gender and disease are presented in Table 1. Carotid stents post-dilated with the Paladin System include the Roadsaver® Carotid Stent (Terumo), the Xact® Carotid Stent (Abbott Vascular), the Cristallo Ideale™ Carotid Self-Expanding Stent (Medtronic), the Wallstent® Endoprosthesis (Boston Scientific), the Precise® Stent (Cordis) and the Adapt™ Monorail (Boston Scientific). The combined major adverse event (MAE) rate at 30 days for all stroke, myocardial infarction and death was 0.98%. There was one major stroke caused by acute stent thrombosis at day 12 (antiplatelet non-compliance). The MAE rate at discharge was 0%. No events were related to the use of the Paladin System. The procedural success rate was 100%, and the technical success was 99%.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Paladin Study (n=106)</th>
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<tbody>
<tr>
<td>Age, SD (min, max)</td>
<td>69.6, 8.3 (47, 88)</td>
</tr>
<tr>
<td>Gender Male</td>
<td>74.5</td>
</tr>
<tr>
<td>Diabetics %</td>
<td>37.1</td>
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<tr>
<td>Hypertension %</td>
<td>82.1</td>
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<tr>
<td>Hyperlipidemia %</td>
<td>84</td>
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<tr>
<td>Current Smoker %</td>
<td>33</td>
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<tr>
<td>Symptomatic %</td>
<td>19.8</td>
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<tr>
<td>Lesion Length, SD (Min, Max)</td>
<td>14.8, 6.3 (3.4, 40.0)</td>
</tr>
<tr>
<td>% diameter stenosis, SD (min, max)</td>
<td>83.6, 8.6 (50, 99)</td>
</tr>
<tr>
<td>History of Neck Radiation %</td>
<td>5.7</td>
</tr>
</tbody>
</table>
Conclusion: The Paladin System is substantially equivalent to the predicate devices with respect to indications for use, labeling, materials, mode of operation and technological characteristics.