December 6, 2018

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

Re:  K181529

Trade/Device Name:  Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection
Regulation Number:  21 CFR 870.1250
Regulation Name:  Percutaneous Catheter
Regulatory Class:  Class II
Product Code:  LIT, NTE
Dated:  November 6, 2018
Received:  November 8, 2018

Dear Ms. 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/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/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,

Misti L. Malone -S

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

Device Name
Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection

Indications for Use (Describe)
The Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection is indicated for percutaneous transluminal angioplasty (PTA) and capture and removal of embolic material during angioplasty, for the femoral, iliac, popliteal and profunda arteries. The System is not intended for use in the renal, cerebral, coronary or carotid vasculature.

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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**510(k) Summary [per 21 CFR 807.92]**

**Date Prepared:** November 05, 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:** Vanguard IEP® Peripheral Balloon Angioplasty System with Integrated Embolic Protection  

**Common Name:** Percutaneous Transluminal Angioplasty Balloon Catheter  

**Device Classification:** Class II (special controls)  

**Regulation Number:** 870.1250  

**Classification Name:** Catheter, Percutaneous  

**Product Code:** LIT, NTE

**Device Description:** The Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection platform is similar to a catheter with a typical angioplasty balloon, but between the distal end of the balloon and the distal tip of the catheter, there is a nitinol-based filter. The device is over-the-wire (OTW) and is 0.018” guidewire compatible. The balloon catheter comes in sizes of 5 and 6 mms outside diameter (OD) and lengths 40, 80, 120 and 200 mms. The filter component is composed of a nitinol filter frame with an overlying membrane perforated with a set pattern of drilled holes. The balloon catheter shaft consists of a dual lumen inner shaft placed inside a single lumen outer shaft. The inner shaft extends beyond the balloon up to the distal catheter tip. Radiopaque markers placed on either side of the balloon and the distal tip of the filter assist with accurate placement. The nitinol filter frame has radiopaque markers, making the diameter of the filter visible when opened. The proximal end of the nitinol frame slides freely over the distal shaft. A pull-wire attaches the handle to the filter frame to activate the filter.

**Indications for Use:** The Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection is indicated for percutaneous transluminal angioplasty (PTA) and capture and removal of embolic material during angioplasty, for the femoral, iliac, popliteal and profunda arteries. The System is not intended for use in the renal, cerebral, coronary or carotid vasculature.

**Predicate Device(s):**  
1. Proteus™ (AngioSlide) (K172494) – Primary Predicate  
2. SpiderFX Embolic Protection Device (Medtronic) (K111010)
### Reference
3. Sterling Monorail PTA Balloon Dilatation Catheter (K141150, Boston Scientific)
4. RX Accunet (K153086, Abbott Vascular)

### Predicates:
3. Sterling Monorail PTA Balloon Dilatation Catheter (K141150, Boston Scientific)
4. RX Accunet (K153086, Abbott Vascular)

### Substantial Equivalency Table

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Subject Device</th>
<th>Primary Predicate</th>
<th>Secondary Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) Number</td>
<td>Vanguard IEP®</td>
<td>Proteus™</td>
<td>SpiderFX™ Embolic Protection Device</td>
</tr>
<tr>
<td>Merchant</td>
<td>Contego Medical</td>
<td>AngioSlide</td>
<td>Medtronic</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Vanguard IEP® Peripheral Balloon Angioplasty System with Integrated Embolic Protection</td>
<td>Proteus PTA Catheter with Embolic Capture Feature</td>
<td>SpiderFX Embolic Protection Device</td>
</tr>
<tr>
<td>Common name</td>
<td>Percutaneous Transluminal Angioplasty Balloon Catheter</td>
<td>Percutaneous Transluminal Angioplasty Balloon Catheter</td>
<td>Embolic Protection Device</td>
</tr>
<tr>
<td>Classification</td>
<td>Class II (21 CFR 870.1250)</td>
<td>Class II (21 CFR 870.1250)</td>
<td>Class II (21 CFR 870.1250)</td>
</tr>
<tr>
<td>Classification name</td>
<td>Catheter, Percutaneous</td>
<td>Catheter, Percutaneous</td>
<td>Percutaneous Catheter</td>
</tr>
<tr>
<td>Product code</td>
<td>LIT</td>
<td>LIT</td>
<td>LIT</td>
</tr>
<tr>
<td>Intended use / Indications for use</td>
<td>The Vanguard IEP® Peripheral Balloon Angioplasty System with Integrated Embolic Protection is indicated for percutaneous transluminal angioplasty (PTA) and capture and removal of embolic material during angioplasty, for the femoral, iliac, popliteal and profunda arteries.</td>
<td>The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and removal of embolic material (e.g. debris, thrombus) during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries. The PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.</td>
<td>The SpiderFX™ Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.</td>
</tr>
<tr>
<td>Principles of Operation</td>
<td>Combines balloon angioplasty and distal embolic particle capture and removal. During balloon dilation, embolic debris is captured by the filter. Upon completion of the intervention the filter is allowed to collapse and the entire system is withdrawn through the introducer sheath or guide catheter.</td>
<td>Combines balloon angioplasty and proximal embolic particle capture and removal. During balloon dilation, negative pressure creates suction to capture embolic debris. Upon completion of the intervention the balloon is collapsed and the entire system is withdrawn through the introducer sheath or guide catheter.</td>
<td>The device serves as both guidewire for interventional devices and a distal embolic capture and removal filter. The filter is removed following angioplasty through a custom removal catheter that is also used to deliver the filter at the onset of the procedure (dual-ended SpiderFX Catheter).</td>
</tr>
<tr>
<td>Sterilization</td>
<td>EO gas</td>
<td>EO gas</td>
<td>EO gas</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>Sterility Assurance Level (SAL)</td>
<td>$10^{-6}$</td>
<td>$10^{-6}$</td>
<td>$10^{-6}$</td>
</tr>
<tr>
<td>Single use</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Shelf life</td>
<td>1 year</td>
<td>3 years</td>
<td>2 years</td>
</tr>
<tr>
<td>Packaging system</td>
<td>Packaged in a PET/G thermoformed tray with lid, sealed in a sterile pouch and single unit box.</td>
<td>Information is not available.</td>
<td>Packaged in a protective hoop, tray, sterile pouch and in a single unit box.</td>
</tr>
<tr>
<td>Catheter Platform</td>
<td>OTW</td>
<td>OTW</td>
<td>OTW, converts to RX</td>
</tr>
<tr>
<td>Radiopaque Markers</td>
<td>Two markers distal and proximal to both filter and balloon. Five gold circumferential markers on the proximal perimeter of the filter frame are visible when filter is open.</td>
<td>Two balloon markers distal and proximal to balloon.</td>
<td>Two marker bands distal and proximal to the filter. A gold radiopaque Proximal Mouth Indicator is visible when filter is open.</td>
</tr>
<tr>
<td>Angioplasty Balloon Characteristics</td>
<td>Nylon, semi-compliant PTA balloon</td>
<td>Semi-compliant PTA balloon</td>
<td>N/A</td>
</tr>
<tr>
<td>Usable Catheter Length</td>
<td>135 cm</td>
<td>135 cm</td>
<td>140 cm</td>
</tr>
<tr>
<td>Guidewire compatibility</td>
<td>0.018&quot;</td>
<td>0.014&quot; and 0.035&quot;</td>
<td>0.014&quot; and 0.018&quot;</td>
</tr>
<tr>
<td>Introducer sheath compatibility</td>
<td>All sizes 6F except for 8 mm diameter balloon sizes are 7F</td>
<td>various: 5F, 6F and 7F</td>
<td>6 F</td>
</tr>
<tr>
<td>Filter Size (diameter)</td>
<td>Adjustable up to 8 mm diameter</td>
<td>N/A</td>
<td>5.0 mm, 6.0 mm, 7.0 mm</td>
</tr>
<tr>
<td>Filter Length</td>
<td>16 mm</td>
<td>N/A</td>
<td>23 mm, 24 mm (7.0 diameter)$^1$</td>
</tr>
<tr>
<td>Reference Vessel Diameters</td>
<td>up to 8 mm</td>
<td>3 mm -6 mm</td>
<td>3 mm -6 mm</td>
</tr>
<tr>
<td>Pore Size</td>
<td>150 micron</td>
<td>N/A</td>
<td>&lt; 200 micron$^2$</td>
</tr>
<tr>
<td>Filter Materials</td>
<td>nitinol, polyurethane</td>
<td>N/A</td>
<td>nitinol mesh</td>
</tr>
<tr>
<td>Balloon diameter [mm]</td>
<td>5 mm – 6 mm</td>
<td>3 mm – 6 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Balloon length [mm]</td>
<td>40 mm, 80 mm, 120 mm and 200 mm</td>
<td>20 mm, 40 mm, 60 mm, 80 mm, 100 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Balloon RBP [atm]</td>
<td>Various: 12 and 14 atm</td>
<td>Various: 12 and 14 atm</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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1 Per SpiderFX IFU, these diameters when delivered at maximum vessel size.

In vitro bench testing of the Vanguard IEP System was conducted in accordance with Contego Medical's risk analysis and all applicable FDA guidance documents and international standards, including:

- ISO 10555-1 – Sterile, Single Use Intravascular Catheters – Part 1: General Requirements
- ISO 10555-4 – Sterile, Single Use Intravascular Catheters – Part 4: Balloon Dilatation Catheters

Bench testing was conducted on sterilized, finished devices, unless otherwise specified. The following testing was completed:

- Dimensional Verification
- Simulated Use
- Torque Response
- Stent Compatibility
- Balloon Rated Burst Pressure / Balloon Compliance
- Balloon Fatigue
- Balloon Inflation and Deflation
- Filter flow characterization
- Embolic Capture Efficiency and Retrieval Ability
- Filter Capacity
- Resistance to Filter Rupture during removal of a fully loaded filter
- Balloon Rated Burst Pressure (constrained and unconstrained)
- Balloon Fatigue (constrained and unconstrained)

**Packaging**

Packaging validation was performed following environmental conditioning, per recognized standards, ASTM D4169, ASTM F2096-11 and ASTM F88/F88M.

**Biocompatibility**

Biocompatibility testing, per ISO 10993-1 included the following tests: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material Mediated Pyrogen, Hemolysis, Complement Activation, Thrombogenicity.

**Sterilization**

Sterilization validation has been performed per ISO 11135:2014 for products sterilized with Ethylene Oxide. EO residuals were tested per ISO 10993-7.

**Animal Testing**

Three GLP animal studies with acute and 28-day endpoints assessed the safety and performance of the Contego Medical catheter platform in the swine model. The ability to capture injected thrombus and successfully retrieve the thrombus was demonstrated. Acute and 28-day histological analysis showed no local injury in the treated arteries and optimal local toleration. There was no evidence of embolization in the dependent tissues from either the Day 0 or Day 28 animal.
Clinical Study

The ENTRAP Study

A prospective, multicenter study to evaluate acute safety and clinical performance of the Vanguard IEP Peripheral Balloon Angioplasty System (ENTRAP Study) was conducted at nine centers in Belgium and Germany. The conduct of this study is in compliance with ISO 14155:2011, Good Clinical Practices (GCP) and the Declaration of Helsinki.

The study enrolled and treated 113 subjects, of which 112 were available for 30-day follow-up. All subjects presented with evidence of peripheral vascular disease. Mean age was 67.4 ± 10.3 years. The study population was predominantly male (63.7%). Among the major risk factors, 28.3% of subjects had diabetes, 54% had hyperlipidemia, and 70.8% were hypertensive. 71.7% were either past or current smokers.

The vessels treated included superficial femoral arteries (75.2%), external iliac arteries (9.7%), common iliac arteries (8.9%), popliteal arteries (4.4%) and common femoral arteries (1.8%)

All enrolled subjects were successfully treated with the study device.

Both primary endpoints, assessing safety (Freedom from MAE, defined as death, amputation and target vessel revascularization at 30 days post-procedure) as well as effectiveness (Procedural Success is defined as <50% residual stenosis without any MAE prior to hospital discharge), were met. The 30-day rate of freedom from MAE was 100.0% with a corresponding exact 97.5% lower confident limit of 0.9616 (i.e. 96.2%) which is lower than the prespecified PG of 88%.

Conclusion

The Vanguard IEP System is substantially equivalent to the predicate devices with respect to indications for use, labeling, materials, mode of operation and technological characteristics.