June 9, 2022

Contego Medical, LLC.
James Clossick
Vice President of Regulatory Affairs
3801 Lake Boone Trail, Suite 100
Raleigh, North Carolina 27607

Re: K221339
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: NTE, LIT
Dated: May 10, 2022
Received: May 11, 2022

Dear James Clossick:

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,

For

Misti Malone
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221339

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

Indications for Use *(Describe)*
The Paladin Carotid PTA Balloon 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 Carotid PTA Balloon System with Integrated Embolic Protection (IEP) should always be used in conjunction with an available embolic protection device when used for post-dilation of self-expanding stents.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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) - K221339

Date Prepared	May 26, 2022
Applicant:	Contego Medical, Inc. 3801 Lake Boone Trail, Suite 100 Raleigh, NC 27607
FDA RegistrationNumber	3011471056
Contact Person:	Mr. Jim Clossick Contego Medical, Inc. 3801 Lake Boone Trail, Suite 100 Raleigh, NC 27607 Phone: + 1 305 607 1708 Email: Jclossick@contegomedical.com
Proprietary Name:	Paladin® System
Common Name:	Paladin Carotid PTA Balloon System with Integrated Embolic Protection
Device Classification:	Class II per 21 CFR §870.1250
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal Temporary Carotid Catheter for Embolic Capture
Product Code:	LIT, NTE
Predicate Device:	Carotid Post-Dilation Balloon System with Integrated Embolic Protection (K181128)

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.

Indication for Use

"The Paladin Carotid PTA Balloon 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 Carotid PTA Balloon System with Integrated Embolic Protection (IEP) should always be used in conjunction with an available embolic protection device when used for post-dilation of self-expanding stents."

Table 4-1. Substantial Equivalency Table

Parameters	Contego Medical Paladin System (modified device)	Contego Medical Paladin System (predicate device K181128)
Indications for use	The Paladin Carotid PTA Balloon 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	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

Parameters	**Contego Medical Paladin System (modified device)**	**Contego Medical Paladin System (predicate device K181128)**
	and removal of embolic material. The diameter of the arterial site for filter deployment should be no more than 7.0 mm. The Paladin Carotid PTA Balloon System with Integrated Embolic Protection (IEP) should always be used in conjunction with an available embolic protection device when used for post-dilation of self-expanding stents.	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.
Common name	Carotid PTA Balloon System with Integrated Embolic Protection	Carotid Post-Dilation Balloon System with Integrated Embolic Protection
Classification	SAME as 510(k) cleared Paladin System	Class II (21 CFR 870.1250)
Classification name	SAME as 510(k) cleared Paladin System	Catheter, Angioplasty, Peripheral, Transluminal Temporary Carotid Catheter for Embolic Capture
Product code	SAME as 510(k) cleared Paladin System	LIT, NTE
Contraindications	SAME as 510(k) cleared Paladin System	Contraindicated for use in coronary arteries. Contraindicated for use in patients who cannot tolerate anticoagulant or anti-platelet therapy Contraindicated for use in patients with known hypersensitivity to nitinol. Contraindicated for use in patients with unresolved bleeding disorders.
Principle of operations	SAME as 510(k) cleared Paladin System	Device operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. 0.014” guidewire compatible catheter based platform with

Parameters	**Contego Medical Paladin System (modified device)**	**Contego Medical Paladin System (predicate device K181128)**
		adjustable nitinol filter frame and urethane filter used to capture and remove embolic material during the carotid angioplasty / post-dilation procedure. Platform is advanced to the carotid lesion, filter is expanded via turning the filter deployment knob on the handle. PTA, or post-dilation of stent, in the carotid is performed, where after the filter is collapsed by turning the knob and the device is removed.
Sterilization	SAME as 510(k) cleared Paladin System	EO gas
Shelf life	SAME as 510(k) cleared Paladin System	12 months
Packaging system	SAME as 510(k) cleared Paladin System	Balloon and filter have a protective sheath. Catheter is protected by a HDPE spiral dispenser, placed in a PET/G snap-top tray, sealed in a sterile pouch. Product is packed in an outer cardboard carton.
Radiopaque markers	SAME as 510(k) cleared Paladin System	Two balloon markers - distal and proximal to balloon. Two marker bands distal and proximal to the filter, and 6 circumferential marker bands on the proximal portion of the filter.
Angioplasty Balloon Characteristics	SAME as 510(k) cleared Paladin System	Nylon semi-compliant PTA balloon
Embolic Capture Mechanism	SAME as 510(k) cleared Paladin System	Self-expanding nitinol filter frame with urethane membrane (40 micron pores) for capture and removal of embolic material from the body
Filter diameter	SAME as 510(k) cleared Paladin System	Adjustable filter fits carotid artery diameters up to 7mm diameter
Usable length [cm]	SAME as 510(k) cleared Paladin System	140
Introducer	SAME as 510(k) cleared	6 F

Parameters	Contego Medical Paladin System (modified device)	Contego Medical Paladin System (predicate device K181128)
sheath compatibility	Paladin System	
Guide wire compatibility	SAME as 510(k) cleared Paladin System	0.014”
Balloon diameter [mm]	SAME as 510(k) cleared Paladin System	5.0 mm and 5.5 mm
Balloon length [mm]	SAME as 510(k) cleared Paladin System	20 mm and 30 mm
Balloon RBP [atm]	SAME as 510(k) cleared Paladin System	14 atm (5.0 mm) 11 atm (5.5 mm)

Performance Data:

The risk analysis activities for the device changes summarized in this Special 510(k) identified that no additional verification or validation activities are required to establish substantial equivalence with predicate devices.

The changes highlighted for the Paladin System do not create any new risks, harms nor were any existing risks altered. No additional risk control measures or mitigations are required.

Conclusion:

The information provided is sufficient to establish the substantial equivalency of the Paladin System (modified device) to the predicate device (Contego Medical, Paladin System 510(k) K181128).

There is no change to device design, its principles of operation or expected performance. The information provided in this submission demonstrates that modified Paladin System is equivalent to the currently cleared Paladin system.