

# K181128 Paladin Carotid Post-dilation Balloon System with Integrated Embolic Protection (Paladin System)

Sep 6, 2018  
129 days to decisionK181128 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k181128/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 30, 2018
Decision date	Sep 6, 2018
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Contego Medical, LLC</b>
Location	Raleigh, NC, US
Contact	Elizabeth Saylor
510(k) history	2 submissions · 2 cleared · 2018-2018

## REGULATORY CONSULTANT

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Consulting firm	<b>Qrac, LLC</b>
Contact	Debra Cogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

## CLINICAL EVIDENCE - NCT02501148

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### A Multi-Center Study to Evaluate Acute Safety and Clinical Performance of Paladin® Carotid Post-Dilation Balloon System With Integrated Embolic Protection

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	106 patients (actual)
Study sites	5 sites
Condition studied	Carotid Artery Stenoses
Study type	Observational
Completion date	Oct 1, 2016
Sponsor	Contego Medical, Inc. (Industry)

### Primary outcome

### Device-related MAE

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02501148](https://clinicaltrials.gov/study/NCT02501148)