

K221339 Paladin Carotid Post-Dilation Balloon System with Integrated Embolic ProtectionJun 9, 2022
31 days to decisionK221339 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k221339/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 9, 2022
Decision date	Jun 9, 2022
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Contego Medical, Inc.
Location	Raleigh, NC, US
Contact	Jim Clossick
510(k) history	5 submissions · 5 cleared · 2022-2025

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