

K181529 Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection

Dec 6, 2018
178 days to decision

K181529 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k181529/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jun 11, 2018
Decision date	Dec 6, 2018
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Qrac, LLC
Contact	Debra Cogan

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

CLINICAL EVIDENCE - NCT03271710

Study to Evaluate the Lower Extremity Intervention With Integrated Embolic Protection Using the Vanguard IEP System

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	113 patients (actual)
Study sites	9 sites
Condition studied	Peripheral Arterial Disease; Intermittent Claudication; Atherosclerosis of Femoral Artery
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 30, 2018
Sponsor	Contego Medical, Inc. (Industry)

Primary outcome

Freedom from MAE, defined as death, amputation and target vessel revascularization (TVR)

Secondary outcome

Technical Success

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03271710

