FDA 510(k) Premarket Notification

CLEARED

K173680 Sapphire II PRO

Mar 1, 2018
90 days to decision

K173680 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k173680/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 1, 2017
Decision date	Mar 1, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orbusneich Medical Trading, Inc.**
Location	Fort Lauderdale, FL, US
Contact	John Pazienza
510(k) history	7 submissions · 7 cleared · 2018-2020

CLINICAL EVIDENCE - NCT03052530

Sapphire II PRO US Clinical Study

Status	Completed
Enrollment	61 patients (actual)
Study sites	4 sites
Condition studied	Coronary Artery Disease; Coronary Disease; Myocardial Ischemia; Heart Diseases; Arteriosclerosis; Cardiovascular Diseases
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 24, 2017
Sponsor	OrbusNeich (Industry)

Primary outcome

Number of Participants With Device Procedural Success

Secondary outcome

Number of Participants With In-hospital Major Adverse Cardiac Events (MACE)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03052530