FDA 510(k) Premarket Notification

K203390 Artimes pro Balloon Dilatation Catheter

CLEARED

Apr 14, 2021
147 days to decision

K203390 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k203390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Nov 18, 2020
Decision date	Apr 14, 2021
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brosmed Medical Co., Ltd.**
Location	Dongguan, CN
Contact	Wade Zhang
510(k) history	8 submissions · 8 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	**Eminence Clinical Research, Inc.**
Contact	Diane Horwitz

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

CLINICAL EVIDENCE - NCT03301246

Artimes Pro Low Profile Dilatation Catheters for Pre-Dilatation in Patients With Symptomatic Ischemic Heart Disease

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	60 patients (actual)
Study sites	2 sites
Condition studied	Coronary Artery Disease; Heart Disease, Ischemic; Coronary Stenosis
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 8, 2020
Sponsor	Eminence Clinical Research, Inc. (Industry)

Primary outcome

Procedure Success

Secondary outcome

Anticipated Adverse Events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03301246