K210839 SoundBite Crossing System - Peripheral (14P)

CLEARED

Apr 20, 2021
29 days to decision

K210839 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k210839/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Mar 22, 2021
Decision date	Apr 20, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Soundbite Medical Solutions, Inc.**
Location	Montreal, CA
Contact	Dominique Abecassis
510(k) history	2 submissions · 2 cleared · 2021-2023

CLINICAL EVIDENCE - NCT03266835

SoundBite™ Crossing System Pivotal Peripheral CTO Crossing Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	15 patients (actual)
Study sites	2 sites
Condition studied	Chronic Total Occlusion of Arteries of the Extremities
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 18, 2019
Sponsor	SoundBite Medical Solutions, Inc. (Industry)

Primary outcome

Technical Device Success

Secondary outcome

Procedural success

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03266835