

K192211 SoundBite Console, SoundBite Active Wire 18Jan 17, 2020
156 days to decisionK192211 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k192211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Aug 14, 2019
Decision date	Jan 17, 2020
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Soundbite Medical Solution, Inc.
Location	Montreal, CA
Contact	Marc Andre Cote
510(k) history	1 submissions · 1 cleared · 2020-2020

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