

K230159 SoundBite® Crossing System XS PeripheralAug 28, 2023
221 days to decisionK230159 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k230159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jan 19, 2023
Decision date	Aug 28, 2023
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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