

K203605 SteriTrakApr 23, 2021
134 days to decisionK203605 · Product code: **JEC** · Orthopedic
Source: <https://www.510kdatabase.net/k203605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Component, Traction, Invasive (JEC)
Date received	Dec 10, 2020
Decision date	Apr 23, 2021
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arbutus Medical, Inc.
Location	Vancouver, CA
Contact	Michael Cancilla
510(k) history	1 submissions · 1 cleared · 2021-2021

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