

K191119 EkoSonic Endovascular DeviceAug 23, 2019
119 days to decisionK191119 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k191119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Apr 26, 2019
Decision date	Aug 23, 2019
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Btg International, Inc.
Location	Bothell, WA, US
Contact	Joshua Kim
510(k) history	6 submissions · 6 cleared · 2014-2019

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