

K182324 EkoSonic Endovascular SystemNov 26, 2018
91 days to decisionK182324 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k182324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Aug 27, 2018
Decision date	Nov 26, 2018
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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