

K183361 EkoSonic Endovascular Device with Control Unit 4.0Apr 5, 2019
122 days to decisionK183361 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k183361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Dec 4, 2018
Decision date	Apr 5, 2019
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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