

**K162771 EkoSonic Endovascular System with Control Unit 4.0**Feb 24, 2017  
144 days to decisionK162771 · Product code: **QEY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162771/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Oct 3, 2016
Decision date	Feb 24, 2017
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Btg International, Inc.</b>
Location	Bothell, WA, US
Contact	CURTIS JENSEN
510(k) history	6 submissions · 6 cleared · 2014-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162771/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026