

**K190267 EZE SIT Valvulotome**Oct 30, 2019  
264 days to decisionK190267 · Product code: **MGZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190267/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valvulotome (MGZ)
Date received	Feb 8, 2019
Decision date	Oct 30, 2019
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lemaitre Vascular</b>
Location	Burlington, MA, US
Contact	John N. Bradsher
510(k) history	3 submissions · 3 cleared · 2018-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190267/> 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 19, 2026