

**K180742 EnsoETM**May 17, 2018  
56 days to decisionK180742 · Product code: **PLA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180742/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Mar 22, 2018
Decision date	May 17, 2018
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Advanced Cooling Therapy, Inc. D/B/A Attune Medical</b>
Location	Chicago, IL, US
Contact	Erik Kulstad
510(k) history	3 submissions · 2 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180742/> 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 May 26, 2026