

**K172029 EnsoETM**Jan 5, 2018  
184 days to decisionK172029 · Product code: **PLA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k172029/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Jul 5, 2017
Decision date	Jan 5, 2018
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Attune Medical</b>
Location	Chicago, IL, US
Contact	Erik Kulstad
510(k) history	2 submissions · 2 cleared · 2017-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172029/> 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 31, 2026