

K180244 EnsoETMFeb 28, 2018
30 days to decisionK180244 · Product code: **PLA** · Cardiovascular
Source: <https://www.510kdatabase.net/k180244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Jan 29, 2018
Decision date	Feb 28, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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