

K172493 EnsoETMOct 17, 2017
60 days to decisionK172493 · Product code: **PLA** · Cardiovascular
Source: <https://www.510kdatabase.net/k172493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Aug 18, 2017
Decision date	Oct 17, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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