

K152450 Esophageal Cooling DeviceJan 15, 2016
140 days to decisionK152450 · Product code: **PLA** · Cardiovascular
Source: <https://www.510kdatabase.net/k152450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Aug 28, 2015
Decision date	Jan 15, 2016
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Cooling Therapy, LLC
Location	Chicago, IL, US
Contact	Erik Kulstad
510(k) history	3 submissions · 2 cleared · 2015-2017

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