

K170009 Esophageal Cooling DeviceMar 30, 2017
86 days to decisionK170009 · Product code: **PLA** · Cardiovascular
Source: <https://www.510kdatabase.net/k170009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Jan 3, 2017
Decision date	Mar 30, 2017
Days to decision	86 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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