

K233357 EsoCool Thermal Regulation CatheterJun 27, 2024
272 days to decisionK233357 · Product code: **PLA** · Cardiovascular
Source: <https://www.510kdatabase.net/k233357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Sep 29, 2023
Decision date	Jun 27, 2024
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nuvaira, Inc.
Location	Maple Grove,, MN, US
Contact	John Carline
510(k) history	1 submissions · 1 cleared · 2024-2024

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