

K254305 BAROguard Donor Lung Preservation SystemJan 30, 2026
30 days to decisionK254305 · Product code: **KDN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k254305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Perfusion, Kidney (KDN)
Date received	Dec 31, 2025
Decision date	Jan 30, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Paragonix Technologies, Inc.
Location	Providence, MA, US
Contact	Julia Bryant
510(k) history	7 submissions · 5 cleared · 2013-2026

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