

K223874 BAROguardAug 15, 2023
235 days to decisionK223874 · Product code: **KDN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k223874/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Dec 23, 2022
Decision date	Aug 15, 2023
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paragonix Technologies
Location	Braintree, MA, US
Contact	Nathan Yetton
510(k) history	5 submissions · 5 cleared · 2018-2024

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