

K211224 RM4 Control UnitOct 15, 2021
175 days to decisionK211224 · Product code: **KDN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Apr 23, 2021
Decision date	Oct 15, 2021
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Institut Georges Lopez
Location	Lissieu, FR
Contact	Matthieu Prouteau
510(k) history	3 submissions · 3 cleared · 2021-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211224/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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