

K221386 PERF-GEN Pulsatile Perfusion SolutionJun 14, 2022
32 days to decisionK221386 · Product code: **KDL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Perfusion, Kidney, Disposable (KDL)
Date received	May 13, 2022
Decision date	Jun 14, 2022
Days to decision	32 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/k221386/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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