

K230193 Servator P Plus SALF SolutionSep 21, 2023
240 days to decisionK230193 · Product code: **KDN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Jan 24, 2023
Decision date	Sep 21, 2023
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	S.A.L.F. Spa
Location	Cenate Sotto, IT
Contact	Carmelo Gagliano
510(k) history	6 submissions · 6 cleared · 2017-2023

REGULATORY CONSULTANT

Consulting firm	The 510k Consulting, LLC
Contact	Joyce St. Germain

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230193/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026