

**K202652 Servator P SALF Solution with THAM**Aug 19, 2021  
339 days to decisionK202652 · Product code: **KDN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k202652/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Sep 14, 2020
Decision date	Aug 19, 2021
Days to decision	339 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>The 510k Consulting, LLC</b>
Contact	Joyce St. Germain

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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