FDA 510(k) Premarket Notification

K230193 Servator P Plus SALF Solution

CLEARED

Sep 21, 2023
240 days to decision

K230193 · Product code: **KDN** · Gastroenterology & Urology
Source: 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