FDA 510(k) Premarket Notification

K211842 Servator M SALF Solution

CLEARED

Dec 20, 2021
188 days to decision

K211842 · Product code: **KDL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k211842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Perfusion, Kidney, Disposable (KDL)
Date received	Jun 15, 2021
Decision date	Dec 20, 2021
Days to decision	188 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