FDA 510(k) Premarket Notification

CLEARED

K212200 STERLINKTM FPS-15s Plus Sterilizer with STERLOADTM Cassette

Oct 22, 2021
100 days to decision

K212200 · Product code: **MLR** · General Hospital
Source: https://www.510kdatabase.net/k212200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Chemical (MLR)
Date received	Jul 14, 2021
Decision date	Oct 22, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Plasmapp Co,., Ltd.**
Location	Daejeon, KR
Contact	LEE Seung Hun
510(k) history	8 submissions · 8 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**CardioMed Device Consultants, LLC**
Contact	Candace Cederman

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