

K233132 PRIMUS Healthcare Sterilizer (Model PSS11-HA & PSS11-HB)Dec 19, 2023
83 days to decisionK233132 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k233132/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Sterilizer, Steam (FLE)
Date received	Sep 27, 2023
Decision date	Dec 19, 2023
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Primus Sterilizer Company, LLC
Location	Great Bend, KS, US
Contact	Patrick Hansen
510(k) history	4 submissions · 4 cleared · 2009-2023

REGULATORY CONSULTANT

Consulting firm	IZiel Healthcare
Contact	Ankur Naik

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/k233132/> 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 26, 2026