

K221474 PRIMUS Healthcare Sterilizer (Model PSS11-HC)Feb 10, 2023
266 days to decisionK221474 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k221474/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Sterilizer, Steam (FLE)
Date received	May 20, 2022
Decision date	Feb 10, 2023
Days to decision	266 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221474/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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