CLEARED

Sep 28, 2022
29 days to decision

K222615 SYSTEM 1E Liquid Chemical Sterilant Processing System, SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6800, SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900, S40 Sterilant Concentrate

K222615 · Product code: **MED** · General Hospital
Source: https://www.510kdatabase.net/k222615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilant, Medical Devices (MED)
Date received	Aug 30, 2022
Decision date	Sep 28, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**STERIS Corporation**
Location	Mentor, OH, US
Contact	Jennifer Nalepka
510(k) history	204 submissions · 202 cleared · 1997-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222615/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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