

K211607 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

Sep 7, 2021
105 days to decision

K211607 · Product code: **MED** · General Hospital
Source: <https://www.510kdatabase.net/k211607/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilant, Medical Devices (MED)
Date received	May 25, 2021
Decision date	Sep 7, 2021
Days to decision	105 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/k211607/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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