

K210737 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

May 12, 2021
62 days to decision

K210737 · Product code: **MED** · General Hospital
Source: <https://www.510kdatabase.net/k210737/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilant, Medical Devices (MED)
Date received	Mar 11, 2021
Decision date	May 12, 2021
Days to decision	62 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

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Device record: <https://www.510kdatabase.net/k210737/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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