

**K212424 AMSCO 400 Small Steam Sterilizers, AMSCO 400
Medium Steam Sterilizers**Oct 28, 2021
85 days to decisionK212424 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k212424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sterilizer, Steam (FLE)
Date received	Aug 4, 2021
Decision date	Oct 28, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212424/>. 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 13, 2026