

K222543 AMSCO 600 Steam Sterilizer, V-PRO maX 2 Low Temperature Sterilization System, V-PRO s2 Low Temperature Sterilization System, RAS 12 Rack, RAS 12 Long Rack, RAS Cycle of the AMSCO 7052HP and 7053HP Single Chamber Washer Disinfector

Aug 25, 2022
3 days to decision

K222543 · Product code: NVE · General Hospital
Source: <https://www.510kdatabase.net/k222543/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Washer, Cleaner, Automated, Endoscope (NVE)
Date received	Aug 22, 2022
Decision date	Aug 25, 2022
Days to decision	3 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Steris
Location	Mentor, OH, US
Contact	Anthony Piotrkowski
Website	https://www.steris.com
510(k) history	21 submissions · 19 cleared · 2021-2026

Steris is a leading global provider of products and services supporting patient care with emphasis on infection prevention. The company operates with a manufacturing facility in Mentor, Ohio, and serves hospitals, surgery centers, pharmaceutical manufacturers, and research laboratories worldwide. Steris has received FDA 510(k) clearances from total submissions since 2021. The company specializes in General Hospital devices, which represent 81% of its regulatory submissions. Recent clearances include sterilization systems, chemical indicators, biological indicators, and wa...