

K233654 VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems

Dec 8, 2023
24 days to decision

K233654 · Product code: JOJ · General Hospital
Source: <https://www.510kdatabase.net/k233654/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	Nov 14, 2023
Decision date	Dec 8, 2023
Days to decision	24 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...