

K163587 VERIFY Incubator for Assert Self Contained Biological IndicatorsMar 24, 2017
94 days to decisionK163587 · Product code: **OWP** · General Hospital
Source: <https://www.510kdatabase.net/k163587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biological Sterilization Process Indicator With Recombinant-dna Plasmid (OWP)
Date received	Dec 20, 2016
Decision date	Mar 24, 2017
Days to decision	94 days
Third-party review	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/k163587/>; 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 June 1, 2026