

K162701 VERIFY Assert Self-Contained Biological Indicator

Mar 24, 2017
177 days to decision

K162701 · Product code: **OWP** · General Hospital
Source: <https://www.510kdatabase.net/k162701/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biological Sterilization Process Indicator With Recombinant-dna Plasmid (OWP)
Date received	Sep 28, 2016
Decision date	Mar 24, 2017
Days to decision	177 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.net

Device record: <https://www.510kdatabase.net/k162701/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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