

K181442 VERIFY Assert Self-Contained Biological Indicator

Jun 13, 2018
 12 days to decision

K181442 · Product code: **OWP** · General Hospital
 Source: <https://www.510kdatabase.net/k181442/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Biological Sterilization Process Indicator With Recombinant-dna Plasmid (OWP)
Date received	Jun 1, 2018
Decision date	Jun 13, 2018
Days to decision	12 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/k181442/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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