

K162945 VERIFY ASSERT STEAM Process Challenge DeviceApr 28, 2017
189 days to decisionK162945 · Product code: **OWP** · General Hospital
Source: <https://www.510kdatabase.net/k162945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biological Sterilization Process Indicator With Recombinant-dna Plasmid (OWP)
Date received	Oct 21, 2016
Decision date	Apr 28, 2017
Days to decision	189 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	STERIS Corporation
Location	Mentor, OH, US
Contact	Ganga Kolli
510(k) history	204 submissions · 202 cleared · 1997-2026

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