

## K233026 Midmark Smart M9® Sterilizer, Midmark Smart M11® Sterilizer

Apr 4, 2024  
195 days to decision

K233026 · Product code: FLE · General Hospital  
Source: <https://www.510kdatabase.net/k233026/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Sep 22, 2023
Decision date	Apr 4, 2024
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Midmark Corporation</b>
Location	Torrance, CA, US
Contact	Adam Clutter
Website	<a href="http://www.midmark.com/">http://www.midmark.com/</a>
510(k) history	5 submissions · 5 cleared · 2016-2025

Midmark Corporation is a leading manufacturer of medical, dental, and veterinary care environment solutions with a manufacturing facility in Torrance, California. Founded in 1915, the company designs integrated equipment and systems for healthcare providers across multiple specialties. Midmark has received FDA 510(k) clearances from total submissions since 2016. The company maintains an active regulatory presence, with its most recent clearance in 2025. Its cleared devices span General Hospital sterilization systems, dental delivery and imaging equipment, and cardiovascul...