

K163337 Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers and Ritter M9D AutoClave® Automatic Sterilizer

Aug 31, 2017
276 days to decision

K163337 · Product code: FLE · General Hospital
Source: <https://www.510kdatabase.net/k163337/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Nov 28, 2016
Decision date	Aug 31, 2017
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Midmark Corporation
Location	Torrance, CA, US
Contact	ADAM CLUTTER
Website	http://www.midmark.com/
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...