FDA 510(k) Premarket Notification

**CLEARED**

# K253196 Midmark 800 Digital Vital Signs Device (1-300-0100, 1-300-0200, 1-300-0300, 1-300-0400)

Jun 12, 2026
259 days to decision

K253196 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k253196/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Sep 26, 2025 |
| Decision date | Jun 12, 2026 |
| Days to decision | 259 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Midmark Corporation** |
| Location | Torrance, CA, US |
| Contact | Jessica Hembrey |
| Website | http://www.midmark.com/ |
| 510(k) history | 6 submissions · 6 cleared · 2016-2026 |

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...