FDA 510(k) Premarket Notification

K161909 IQvitals Zone

CLEARED

Nov 17, 2016
128 days to decision

K161909 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k161909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 12, 2016
Decision date	Nov 17, 2016
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Midmark Corporation**
Location	Torrance, CA, US
Contact	Asad Abu-Tarif
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...