FDA 510(k) Premarket Notification

CLEARED

K250135 WAVE Clinical Platform (2.0.000)

Jan 16, 2026
364 days to decision

K250135 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k250135/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jan 17, 2025
Decision date	Jan 16, 2026
Days to decision	364 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corp/ Excel Medical**
Location	Palm Beach Gardens, FL, US
Contact	Gena Wolfe
510(k) history	1 submissions · 1 cleared · 2026-2026