FDA 510(k) Premarket Notification

K232111 NeoBeat, NeoBeat Mini

CLEARED

Jun 25, 2024
347 days to decision

K232111 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k232111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 14, 2023
Decision date	Jun 25, 2024
Days to decision	347 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Laerdal Medical AS**
Location	Stavanger, NO
Contact	Mari Kaada
510(k) history	5 submissions · 5 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**MED Institute**
Contact	Daniel J. Dillon, M.S., RAC

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov