

K260050 WRAP System

Jul 15, 2026
189 days to decision

K260050 · Product code: MNR · Neurology
Source: <https://www.510kdatabase.net/k260050/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 7, 2026
Decision date	Jul 15, 2026
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huneo, LLC
Location	Willoughby Hills, OH, US
Contact	Philip Ryder
510(k) history	1 submissions · 1 cleared · 2026-2026