FDA 510(k) Premarket Notification

CLEARED

K253436 c-med0 alpha

Apr 30, 2026
211 days to decision

K253436 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k253436/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Oct 1, 2025
Decision date	Apr 30, 2026
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cosinuss GmbH**
Location	Munich, DE
Contact	Ralph Heim
Website	https://cosinuss.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Cosinuss GmbH is a medical device company with a manufacturing facility in Munich, Germany. The company develops and manufactures Cardiovascular devices for clinical and patient care applications. The company has received FDA 510(k) clearance from total submission. Cosinuss GmbH specializes in Cardiovascular devices, representing the entirety of its FDA 510(k) regulatory submissions. The company achieved its first FDA 510(k) clearance in 2026 and remains active in regulatory submissions. Explore the company's cleared device names, product codes, and clearance dates in the...