FDA 510(k) Premarket Notification

K241217 CloudHRV™ System (100-01-001)

CLEARED

Jan 16, 2025
260 days to decision

K241217 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k241217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 1, 2024
Decision date	Jan 16, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inmedix, Inc.**
Location	Normandy Park, WA, US
Contact	Andrew Holman
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Daniel & Daniel Consulting, LLC**
Contact	Michael Daniel

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