

K243981 Hexoskin Medical System (7100-00016)Nov 18, 2025
330 days to decisionK243981 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k243981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Dec 23, 2024
Decision date	Nov 18, 2025
Days to decision	330 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carre Technologies, Inc.
Location	Montreal, CA
Contact	Jean-François Roy
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT05970328**Hexoskin Medical System - ECG Performance Testing**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	75 patients (actual)
Study sites	2 sites
Condition studied	Cardiac Rhythm Disturbance
Study type	Observational
Completion date	Feb 17, 2024
Sponsor	Carré Technologies Inc. (Industry)

Primary outcome

ECG characteristics measurement agreement

Secondary outcome

Heart rate agreement

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05970328