

**K252984 Perin Health System (PHD80060-2)**Jan 22, 2026  
126 days to decisionK252984 · Product code: **DRG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252984/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Sep 18, 2025
Decision date	Jan 22, 2026
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Perin Health Devices, LLC</b>
Location	Oklahoma City, OK, US
Contact	Ian McLane
Website	<a href="https://perinhealthdevices.com">https://perinhealthdevices.com</a>
510(k) history	1 submissions · 1 cleared · 2026-2026

Perin Health Devices, LLC develops wearable medical devices and integrated care management systems for remote patient monitoring. The company is based in Oklahoma City with FDA-registered manufacturing operations in the same location. Their flagship product, the Health Patch, is a multi-modal wearable that monitors up to 15 vital metrics simultaneously. The company has received FDA 510(k) clearance from total submission, with all submissions focused on Cardiovascular devices. The latest clearance was in 2026, confirming active regulatory engagement and current market pres...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Rook Quality Systems</b>
Contact	Tyler Ting

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

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