

K141813 RHYTHMSTAR SYSTEMAug 5, 2014
29 days to decisionK141813 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k141813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jul 7, 2014
Decision date	Aug 5, 2014
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	RhythMedix, LLC
Location	Minneapolis, MN, US
Contact	M.W.(ANDY) ANDERSON
Website	https://rhythmedix.com
510(k) history	3 submissions · 3 cleared · 2014-2026

RhythMedix, LLC is a U.S.-based cardiac monitoring company founded in 2013. The company develops wearable cardiac monitoring devices with integrated cellular connectivity for arrhythmia detection and management. RhythMedix operates with a fully integrated model combining device technology, manufacturing, software, and 24/7 clinical monitoring services. The company has received FDA 510(k) clearances from total submissions since 2014. RhythMedix specializes exclusively in Cardiovascular devices, with its primary product line focused on remote cardiac monitoring systems. The...
