FDA 510(k) Premarket Notification

CLEARED

K243781 HemoSphere Advanced Monitor (HEM1)

Jul 23, 2025
226 days to decision

K243781 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k243781/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 9, 2024
Decision date	Jul 23, 2025
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HemoSphere Technology Module (HEMTOM10); HemoSphere ClearSight Module (HEMCSM10); Smart Pressure Controller (PC1Q); Acumen IQ Plus Finger Cuff (AIQCA2); HemoSphere Pressure Cable (HEMPSC100); HemoSphere Vita Monitor (HEMVITA1); HemoSphere Vita Technology Module (HEMVTOM1); HemoSphere VitaWave module (HEMVWM1); VitaWave Plus finger cuff (VWCA2)

APPLICANT

Company	**Edwards Lifesciences**
Location	Irvine, CA, US
Contact	Varad Raghuwanshi
Website	http://www.edwards.com
510(k) history	20 submissions · 19 cleared · 2011-2026

Edwards Lifesciences is the leading global structural heart innovation company dedicated to improving patient lives through breakthrough cardiovascular technologies. The company partners with physicians to develop products for patients fighting heart disease, with a manufacturing facility in Irvine, US. Edwards Lifesciences has received FDA 510(k) clearances from total submissions since 2011. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance in 2025 reflects continued innovation and acti...