

K252389 Rhythm Master ECG Patch (HM-15BB-AX, HM-15BW-AX, HM-15BW-DX)Apr 23, 2026
266 days to decisionK252389 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k252389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Jul 31, 2025
Decision date	Apr 23, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smwmed, Inc.
Location	San Diego, CA, US
Contact	Bo Pi
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Feiying Drug & Medical Consulting Technical Service Group
Contact	Youshan Gong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026