

K242583 AT-Patch (ATP-C130/ATP-C70)May 2, 2025
245 days to decisionK242583 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k242583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Aug 30, 2024
Decision date	May 2, 2025
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Atsens Co., Ltd.
Location	Seongnam-Si, KR
Contact	KeonHoon Lee
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Bt Solutions, Inc.
Contact	Do Hyun Kim

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242583/> 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