

K231289 S-Patch Ex Wearable ECG PatchAug 30, 2023
118 days to decisionK231289 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k231289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	May 4, 2023
Decision date	Aug 30, 2023
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wellysis Corp.
Location	Seoul, KR
Contact	DoGyun Im
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Nikki Batista

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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