

K203638 AT-Patch ECG Analysis SystemOct 12, 2022
667 days to decisionK203638 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k203638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Dec 14, 2020
Decision date	Oct 12, 2022
Days to decision	667 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/k203638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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