

K203168 LifeLens Wireless ECG MonitorJul 20, 2021
270 days to decisionK203168 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k203168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Oct 23, 2020
Decision date	Jul 20, 2021
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	LifeLens Technologies, Inc.
Location	Warminster, PA, US
Contact	Landy Toth
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Nicole 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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