FDA 510(k) Premarket Notification

K203168 LifeLens Wireless ECG Monitor

CLEARED

Jul 20, 2021
270 days to decision

K203168 · 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