FDA 510(k) Premarket Notification

K231276 SmartCardia 7L Platform

CLEARED

Aug 30, 2023
120 days to decision

K231276 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k231276/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	May 2, 2023
Decision date	Aug 30, 2023
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smartcardia SA**
Location	Lausanne, CH
Contact	Srinivasan Murali
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Steurer Consulting Group, LLC**
Contact	Robert Steurer

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