FDA 510(k) Premarket Notification

K240653 SmartCardia 7L Platform (MCT)

CLEARED

Oct 31, 2024
238 days to decision

K240653 · Product code: **QYX** · Cardiovascular
Source: https://www.510kdatabase.net/k240653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Mar 7, 2024
Decision date	Oct 31, 2024
Days to decision	238 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