FDA 510(k) Premarket Notification

K232686 CorVista® System

CLEARED

Sep 8, 2023
7 days to decision

K232686 · Product code: **QXX** · Cardiovascular
Source: https://www.510kdatabase.net/k232686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coronary Artery Disease Machine Learning-based Notification Software (QXX)
Date received	Sep 1, 2023
Decision date	Sep 8, 2023
Days to decision	7 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corvista Health, Inc.**
Location	Washington, DC, US
Contact	Gabrielle Zaeska
510(k) history	1 submissions · 1 cleared · 2023-2023