

K220526 HD+12, HD+15May 15, 2023
445 days to decisionK220526 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k220526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Feb 24, 2022
Decision date	May 15, 2023
Days to decision	445 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardioline S.P.A
Location	Cavareno, TN, US
Contact	Antonella Bornacin
510(k) history	4 submissions · 4 cleared · 2015-2023

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