FDA 510(k) Premarket Notification

K142476 Master Caution Device MCD

CLEARED

Feb 17, 2015
167 days to decision

K142476 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k142476/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 3, 2014
Decision date	Feb 17, 2015
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Healthwatch , Ltd.**
Location	Kfar Saba, IL
Contact	Yoram Levy
510(k) history	1 submissions · 1 cleared · 2015-2015