FDA 510(k) Premarket Notification

K173872 FibriCheck

CLEARED

Sep 28, 2018
282 days to decision

K173872 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k173872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Dec 20, 2017
Decision date	Sep 28, 2018
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Qompium NV**
Location	Hasselt, BE
Contact	Jo Van der Auwera
510(k) history	2 submissions · 2 cleared · 2018-2024