FDA 510(k) Premarket Notification

K100040 BIOHARNESS

CLEARED

Dec 3, 2010
330 days to decision

K100040 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k100040/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jan 7, 2010
Decision date	Dec 3, 2010
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zephyr Technology Corporation**
Location	Annapolis, MD, US
Contact	CODE CUBITT
Website	http://zephyranywhere.com/
510(k) history	4 submissions · 4 cleared · 2010-2013