FDA 510(k) Premarket Notification

K143676 B40i Patient Monitor

CLEARED

Jul 31, 2015
219 days to decision

K143676 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k143676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 24, 2014
Decision date	Jul 31, 2015
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Healthcare Finland Oy**
Location	Madison, WI, US
Contact	JOEL KENT
510(k) history	30 submissions · 30 cleared · 2007-2023