FDA 510(k) Premarket Notification

K122253 PROCARE MONITOR B20

CLEARED

Mar 22, 2013
238 days to decision

K122253 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k122253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 27, 2012
Decision date	Mar 22, 2013
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems China Co., Ltd.**
Location	Wuxi, Jiangsu Province, CN
Contact	ROBERT CASARSA
510(k) history	13 submissions · 13 cleared · 2009-2017