FDA 510(k) Premarket Notification

K171580 Monitor B125, Monitor B105

CLEARED

Nov 1, 2017
154 days to decision

K171580 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k171580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 31, 2017
Decision date	Nov 1, 2017
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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