FDA 510(k) Premarket Notification

K102040 PATIENT MONITOR

CLEARED

Sep 24, 2010
67 days to decision

K102040 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k102040/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 19, 2010
Decision date	Sep 24, 2010
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guangdong Biolight Meditech Co., Ltd.**
Location	Shanghai, CN
Contact	ANA HONG
510(k) history	21 submissions · 21 cleared · 2008-2019