

K100046 M SEIRES PATIENT MONITOR MODEL M66, M69, M8000, M9000, M7000

Apr 8, 2010
90 days to decision

K100046 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k100046/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jan 8, 2010
Decision date	Apr 8, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k100046/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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