FDA 510(k) Premarket Notification

K082789 G1B PULSE OXIMETER

CLEARED

Jan 7, 2009
106 days to decision

K082789 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k082789/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 23, 2008
Decision date	Jan 7, 2009
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**General Meditech, Inc.**
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	2 submissions · 2 cleared · 2009-2010