FDA 510(k) Premarket Notification

K081937 PICOSAT II AND M3002A MULTIMEASUREMENT AND M1020B PLUG-IN MODULES SPO2 PULSE OXIMETRY MODULE

CLEARED

Aug 29, 2008
53 days to decision

K081937 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k081937/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Jul 7, 2008
Decision date	Aug 29, 2008
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medizin Systeme Boeblingen GmbH**
Location	B?blingen, DE
Contact	JENS-PETER SEHER
510(k) history	48 submissions · 48 cleared · 2004-2026