FDA 510(k) Premarket Notification

K132516 OXIPROBE E (OXIPROBE)

CLEARED

Jul 30, 2014
352 days to decision

K132516 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k132516/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 12, 2013
Decision date	Jul 30, 2014
Days to decision	352 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio Medical Technologies Co., Ltd.**
Location	Dunwoody, GA, US
Contact	ELAINE DUNCAN
510(k) history	2 submissions · 2 cleared · 2009-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k132516/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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