FDA 510(k) Premarket Notification

K962156 3304 PULSE OXIMETER

CLEARED

Aug 28, 1996
85 days to decision

K962156 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k962156/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 4, 1996
Decision date	Aug 28, 1996
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bci Intl., Inc.**
Location	Waukesha, WI, US
Contact	DONALD J ALEXANDER
510(k) history	20 submissions · 20 cleared · 1994-1999