FDA 510(k) Premarket Notification

K190399 Beddr 200 System

CLEARED

Aug 5, 2019
167 days to decision

K190399 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k190399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Feb 19, 2019
Decision date	Aug 5, 2019
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Hancock Medical, Inc.**
Location	Mountain View, CA, US
Contact	Tom Goff
510(k) history	1 submissions · 1 cleared · 2019-2019