FDA 510(k) Premarket Notification

K063661 RENU REPROCESSED NELLCOR OXYSENSOR, MODELS D-20 AND I-20

CLEARED

May 25, 2007
168 days to decision

K063661 · Product code: **NLF** · Anesthesiology
Source: https://www.510kdatabase.net/k063661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Reprocessed (NLF)
Date received	Dec 8, 2006
Decision date	May 25, 2007
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Renu Medical, Inc.**
Location	Everett, WA, US
Contact	BRUCE PIERSON
510(k) history	9 submissions · 9 cleared · 2003-2021