CLEARED

Mar 8, 2022
326 days to decision

K211138 Reprocessed Pulse Oximeter Sensor (D-25), Reprocessed Pulse Oximeter Sensor (D-25L), Reprocessed Pulse Oximeter Sensor (D-20), Reprocessed Pulse Oximeter Sensor (N-25), Reprocessed Pulse Oximeter Sensor (I-20), Reprocessed Pulse Oximeter Sensor (Max-A), Reprocessed Pulse Oximeter Sensor (Max-AL), Reprocessed Pulse Oximeter Sensor (Max-P), Reprocessed Pulse Oximeter Sensor (Max-N), Reprocessed Pulse Oximeter Sensor (Max-I)

K211138 · Product code: **NLF** · Anesthesiology
Source: https://www.510kdatabase.net/k211138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Reprocessed (NLF)
Date received	Apr 16, 2021
Decision date	Mar 8, 2022
Days to decision	326 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Sustainability Solutions**
Location	Tempe, AZ, US
Contact	Mia Brown
510(k) history	31 submissions · 31 cleared · 2011-2025