CLEARED

Mar 8, 2022
326 days to decision

K211140 Reprocessed Masimo Pulse Oximeter (1859 Adult O2 Transducer), Reprocessed Masimo Pulse Oximeter (1860 Pediatric O2 Transducer), Reprocessed Masimo Pulse Oximeter (1861 Infant O2 Transducer), Reprocessed Masimo Pulse Oximeter (1862 Adult O2 Transducer), Reprocessed Masimo Pulse Oximeter (2317 Adult O2 Transducer), Reprocessed Masimo Pulse Oximeter (2319 Infant O2 Transducer), Reprocessed Masimo Pulse Oximeter (2320 Adult O2 Transducer), Reprocessed Masimo Pulse Oximeter (2328 Infant O2

K211140 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k211140/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
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	Moira Barton-Varty
510(k) history	31 submissions · 31 cleared · 2011-2025