

**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)**

Mar 8, 2022  
 326 days to decision

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	<b>Stryker Sustainability Solutions</b>
Location	Tempe, AZ, US
Contact	Mia Brown
510(k) history	31 submissions · 31 cleared · 2011-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k211138/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026