

K222019 Reprocessed RD SET Adt Pulse Oximeter Sensor (4000), Reprocessed RD SET Pdt Pulse Oximeter Sensor (4001), Reprocessed RD SET Inf Pulse Oximeter Sensor (4002), Reprocessed RD SET Adt Pulse Oximeter Sensor (4003)

Dec 4, 2022
149 days to decision

K222019 · Product code: **NLF** · Anesthesiology
Source: <https://www.510kdatabase.net/k222019/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Reprocessed (NLF)
Date received	Jul 8, 2022
Decision date	Dec 4, 2022
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

CLINICAL EVIDENCE - NCT05245526

SpO2 Accuracy of Noninvasive Disposable Pulse Oximeter Sensor

Status	Completed
Enrollment	12 patients (actual)
Study sites	1 site
Condition studied	Healthy; Hypoxia
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 20, 2022
Sponsor	Stryker Sustainability Solutions (Industry)

Primary outcome

Accuracy of Sensor by Arms Calculation

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05245526

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k222019/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026