

K201699 Medline ReNewal Reprocessed Nellcor OxiMax SpO2 SensorJul 22, 2020
30 days to decisionK201699 · Product code: **NLF** · Anesthesiology
Source: <https://www.510kdatabase.net/k201699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter, Reprocessed (NLF)
Date received	Jun 22, 2020
Decision date	Jul 22, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Instrument and Savings Inc (Dba Medline Renewal)
Location	Redmond, OR, US
Contact	Stephanie Boyle Mays
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Surgical Instrument Service and Savings Inc.(Dba Medline Ren
Contact	Stephanie Boyle Mays

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201699/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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