

K081927 RENU MEDICAL OXIMETRY SENSOR, ADULT, PED, INF,NEO

Feb 6, 2009
214 days to decision

K081927 · Product code: **NLF** · Anesthesiology
Source: <https://www.510kdatabase.net/k081927/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Reprocessed (NLF)
Date received	Jul 7, 2008
Decision date	Feb 6, 2009
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Renu Medical, Inc.
Location	Everett, WA, US
Contact	L. BRUCE PIERSON
510(k) history	9 submissions · 9 cleared · 2003-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081927/>. Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026