

**K251691 Unimed Reusable SpO2 Sensors (-08 Series)
(U403S-08)**Dec 1, 2025
182 days to decisionK251691 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k251691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 2, 2025
Decision date	Dec 1, 2025
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Unimed Reusable SpO2 Sensors (-08 Series) (U203S-08); Unimed Reusable SpO2 Sensors (-08 Series) (U103S-08); Unimed Reusable SpO2 Sensors (-08 Series) (U103-08)

APPLICANT

Company	Unimed Medical Supplies, Inc.
Location	Mukwonago, WI, US
Contact	Huanyu Zeng
510(k) history	19 submissions · 19 cleared · 2008-2026

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