

K241393 ODI-TechAug 30, 2024
106 days to decisionK241393 · Product code: **MUD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	May 16, 2024
Decision date	Aug 30, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Odi Medical AS
Location	Oslo, NO
Contact	Wenche Groenvold
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241393/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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