

K232385 OxiplexTS200Mar 1, 2024
205 days to decisionK232385 · Product code: **MUD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Aug 9, 2023
Decision date	Mar 1, 2024
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Iss Medical, Inc.
Location	Champaign, IL, US
Contact	Beniamino Barbieri
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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