

K221010 Intra.Ox 2.0 Handheld Tissue OximeterMay 3, 2022
28 days to decisionK221010 · Product code: **MUD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Apr 5, 2022
Decision date	May 3, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vioptix, Inc.
Location	Irvine, CA, US
Contact	Scott Coleridge
510(k) history	9 submissions · 9 cleared · 2005-2025

REGULATORY CONSULTANT

Consulting firm	ViOptix, Inc.
Contact	Mark Lonsinger

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221010/> 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 26, 2026