FDA 510(k) Premarket Notification

**CLEARED**

# K250519 Lap.Ox™ Laparoscopic Tissue Oximeter

Jun 26, 2025
125 days to decision

K250519 · Product code: **MUD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250519/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter, Tissue Saturation (MUD) |
| Date received | Feb 21, 2025 |
| Decision date | Jun 26, 2025 |
| Days to decision | 125 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