

K201976 SnapshotNIRNov 10, 2020
117 days to decisionK201976 · Product code: **MUD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Jul 16, 2020
Decision date	Nov 10, 2020
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kent Imaging
Location	Calgary, CA
Contact	Liz Newell
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201976/> 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 June 28, 2026