

K010382 100 SERIES OXYGEN ANALYZER, MODELS 1000-E AND 1000-I

Mar 1, 2001
21 days to decision

K010382 · Product code: **CCL** · Anesthesiology
Source: <https://www.510kdatabase.net/k010382/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Gas, Oxygen, Gaseous-phase (CCL)
Date received	Feb 8, 2001
Decision date	Mar 1, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sensidyne, Inc.
Location	Clearwater, FL, US
Contact	GEORGE MASON
510(k) history	4 submissions · 4 cleared · 2000-2002

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k010382/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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