FDA 510(k) Premarket Notification

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

CLEARED

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