FDA 510(k) Premarket Notification

K012395 MAC-LINE 02/CO2 NASAL CANNULA SAMPLE LINE

CLEARED

Aug 15, 2001
19 days to decision

K012395 · Product code: **CCK** · Anesthesiology
Source: https://www.510kdatabase.net/k012395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Jul 27, 2001
Decision date	Aug 15, 2001
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oridion Medical 1987 , Ltd.**
Location	Jerusalem, IL
Contact	SANFORD BROWN
510(k) history	19 submissions · 19 cleared · 2001-2020

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k012395/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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