

K132729 ISO-GARD MASKJan 9, 2014
128 days to decisionK132729 · Product code: **CBN** · Anesthesiology
Source: <https://www.510kdatabase.net/k132729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Gas-scavenging (CBN)
Date received	Sep 3, 2013
Decision date	Jan 9, 2014
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflexmedical, Inc.
Location	Jeffrey, NH, US
Contact	Angela Bouse
510(k) history	64 submissions · 61 cleared · 1985-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132729/> 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 May 24, 2026