

K031397 MERLIN E-MASKJul 29, 2004
454 days to decisionK031397 · Product code: **CBP** · Anesthesiology
Source: <https://www.510kdatabase.net/k031397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	May 2, 2003
Decision date	Jul 29, 2004
Days to decision	454 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Merlin Medical Limited
Location	United Kingdom, GB
Contact	ROBERT STEELE
510(k) history	2 submissions · 2 cleared · 2004-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031397/> 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 25, 2026