

K081516 MEDSOURCE CPR MASK WITH & WITHOUT OXYGEN PORT

Aug 26, 2008
88 days to decision

K081516 · Product code: **CBP** · Anesthesiology
Source: <https://www.510kdatabase.net/k081516/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	May 30, 2008
Decision date	Aug 26, 2008
Days to decision	88 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Medsource International, LLC
Location	Indianapolis, IN, US
510(k) history	9 submissions · 9 cleared · 2008-2023

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Device record: <https://www.510kdatabase.net/k081516/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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