

K964092 TMS COMFORT SERIES NASAL CPAP MASKJul 31, 1997
293 days to decisionK964092 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k964092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Oct 11, 1996
Decision date	Jul 31, 1997
Days to decision	293 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tiara Medical Systems, Inc.
Location	Lakewood, OH, US
Contact	NORBERT E CICHON
510(k) history	7 submissions · 7 cleared · 1997-2005

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