

**K914196 RONDEX MASKS MODELS 9015/9011/901102
MODIFIED**Nov 8, 1991
64 days to decisionK914196 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k914196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Sep 5, 1991
Decision date	Nov 8, 1991
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rondex Products, Inc.
Location	Mchenry, IL, US
Contact	GENE R BALDWIN
510(k) history	11 submissions · 10 cleared · 1984-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914196/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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