

**K921002 RONDEX MASK MODELS 9122/91111/9102/911102,  
MODIFIED**

Oct 6, 1992  
224 days to decision

K921002 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k921002/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Feb 25, 1992
Decision date	Oct 6, 1992
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k921002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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