

**K954442 STERILE ISOTONIC SALINE & STERILE WATER**Dec 21, 1995  
87 days to decisionK954442 · Product code: **JOL** · General HospitalSource: <https://www.510kdatabase.net/k954442/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter And Tip, Suction (JOL)
Date received	Sep 25, 1995
Decision date	Dec 21, 1995
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medcare Custom Packaging, Inc.</b>
Location	West Swanzey, NH, US
Contact	CRAIG J BELL
510(k) history	11 submissions · 6 cleared · 1990-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954442/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026