

**K953377 DISTENTION BALLOON**Oct 23, 1995  
96 days to decisionK953377 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k953377/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 19, 1995
Decision date	Oct 23, 1995
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Origin Medsystems, Inc.</b>
Location	San Mateo, CA, US
Contact	ALBERT K CHIN
510(k) history	50 submissions · 49 cleared · 1989-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953377/> 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 May 22, 2026