

**K042412 MODIFIED SPACEMAKER SYSTEM**Sep 24, 2004  
17 days to decisionK042412 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k042412/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 7, 2004
Decision date	Sep 24, 2004
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>United States Surgical, A Division of Tyco Healthc</b>
Location	Mchenry, IL, US
Contact	RENEE ALFANO
510(k) history	218 submissions · 200 cleared · 1977-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042412/> 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 20, 2026