

K944418 THE SPACEMAKER AND THE SPACEMAKER IINov 1, 1994
54 days to decisionK944418 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k944418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 8, 1994
Decision date	Nov 1, 1994
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	General Surgical Innovations
Location	Portola Valley, CA, US
Contact	THERESA M NAZAROFF
510(k) history	14 submissions · 13 cleared · 1993-1999

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