

**K973046 SPACEMAKER SURGICAL BALLOON DISSECTOR,
SPACEMAKER II SURGICAL BALLOON DISSECTOR,
SAPHTRAK**Jan 16, 1998
154 days to decisionK973046 · Product code: **GCJ** · General & Plastic Surgery
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Aug 15, 1997
Decision date	Jan 16, 1998
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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