

**K962702 SPACEMAKER SERIAL SURGICAL BALLOON
DISSECTOR, WITH CANNULA, WITH VISUALIZATION AND
WITH VISUALIZATION AND CANNULA**

Feb 19, 1997
222 days to decision

K962702 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k962702/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 12, 1996
Decision date	Feb 19, 1997
Days to decision	222 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k962702/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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