

K954175 DUO BALLOON SYSTEM (DBS) 1[10 AND 12 MM SIZES]

Nov 9, 1995
65 days to decision

K954175 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k954175/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 5, 1995
Decision date	Nov 9, 1995
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Origin Medsystems, Inc.
Location	San Mateo, CA, US
Contact	RICHARD D RUSH
510(k) history	50 submissions · 49 cleared · 1989-1999

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Device record: <https://www.510kdatabase.net/k954175/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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