

**K946002 ORIGIN PREPERITONEAL DISSECTION BALLOON SYSTEM (PDBS)--EXTRA**

Jan 5, 1995  
44 days to decision

K946002 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k946002/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 22, 1994
Decision date	Jan 5, 1995
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Origin Medsystems, Inc.</b>
Location	San Mateo, CA, US
Contact	SANDRA V DIGGS
510(k) history	50 submissions · 49 cleared · 1989-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k946002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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