

**K032093 PARIEFIX**Oct 22, 2003  
107 days to decisionK032093 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k032093/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 7, 2003
Decision date	Oct 22, 2003
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sofradim Production</b>
Location	Ayer, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	41 submissions · 41 cleared · 1999-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032093/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026