

**K211577 SoftFix Balloon Trocar**Nov 5, 2021  
168 days to decisionK211577 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	May 21, 2021
Decision date	Nov 5, 2021
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Unimax Medical Systems, Inc.</b>
Location	Taipei County, TW
Contact	Monoj Mon Kalita
510(k) history	7 submissions · 7 cleared · 2011-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211577/> 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 26, 2026