

**K252877 SANDRO Dual**Dec 19, 2025  
100 days to decisionK252877 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252877/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 10, 2025
Decision date	Dec 19, 2025
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wontech Co., Ltd.</b>
Location	Daejeon, KR
Contact	Hyunsik Yoon
510(k) history	28 submissions · 28 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252877/> 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 13, 2026