

K232106 Air Gap FiberJan 8, 2024
178 days to decisionK232106 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 14, 2023
Decision date	Jan 8, 2024
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wontech Co., Ltd.
Location	Daejeon, KR
Contact	Hyun Sik Yoon
510(k) history	28 submissions · 28 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232106/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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