

K212127 PicocaremajestyJan 7, 2022
184 days to decisionK212127 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 7, 2021
Decision date	Jan 7, 2022
Days to decision	184 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

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