

**K241643 WONTECH Surgical Optic Fibers
(BA400/BA400R/BA600/BA600R)**Feb 14, 2025
252 days to decisionK241643 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k241643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 7, 2024
Decision date	Feb 14, 2025
Days to decision	252 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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