

K183122 810nm Diode Laser SystemAug 25, 2019
289 days to decisionK183122 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k183122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 9, 2018
Decision date	Aug 25, 2019
Days to decision	289 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Wonderful Opto-Electrics Tech.Co.,Ltd
Location	Shanghai, CN
Contact	Yvonne Xue
510(k) history	6 submissions · 6 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183122/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026