

K163655 SparklingMar 17, 2017
84 days to decisionK163655 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k163655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 23, 2016
Decision date	Mar 17, 2017
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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