

K202828 Surgical Green Laser SystemJun 4, 2021
253 days to decisionK202828 · Product code: **GEX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 24, 2020
Decision date	Jun 4, 2021
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Realton (Suzhou) Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Mingzhu Liu
510(k) history	3 submissions · 3 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Guangzhou Osmunda Medical Device Technical Services Co., Ltd.
Contact	Olivia Meng

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202828/> 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 27, 2026