FDA 510(k) Premarket Notification

# K212978 Diode laser therapy system

**CLEARED**

Nov 10, 2021
54 days to decision

K212978 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212978/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Sep 17, 2021 |
| Decision date | Nov 10, 2021 |
| Days to decision | 54 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Beijing Unt Technology Co., Ltd.** |
| Location | Beijing, CN |
| Contact | Qianwen Sheng |
| 510(k) history | 2 submissions · 2 cleared · 2021-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Mid-Link Consulting Co, Ltd.** |
| Contact | Diana Hong |

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