

**K230580 Diode Laser System**May 26, 2023  
85 days to decisionK230580 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230580/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Mar 2, 2023                             |
| Decision date         | May 26, 2023                            |
| Days to decision      | 85 days                                 |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|--|
| Company        | <b>Smedtrum Medical Technology Co., Ltd.</b> |
| Location       | New Taipei City, TW                          |
| Contact        | Crimson Wu                                   |
| 510(k) history | 5 submissions · 5 cleared · 2022-2024        |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230580/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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