

K231131 Diode Laser Body Sculpture SystemsJun 22, 2023
62 days to decisionK231131 · Product code: **PKT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231131/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laser For Disruption Of Adipocyte Cells For Aesthetic Use (PKT) |
| Date received | Apr 21, 2023 |
| Decision date | Jun 22, 2023 |
| Days to decision | 62 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shanghai Bele Medical Technology Co.,Ltd |
| Location | Shanghai, CN |
| Contact | Jeremy Li |
| 510(k) history | 3 submissions · 3 cleared · 2023-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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