

K231514 Azure

Feb 14, 2024
265 days to decision

K231514 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k231514/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | May 25, 2023 |
| Decision date | Feb 14, 2024 |
| Days to decision | 265 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Daeshin Enterprise Co., Ltd. |
| Location | Guro-Gu, KR |
| Contact | Kyu Kim |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k231514/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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