

K241646 ORTIV (ORTIV-BL, ORTIV-WH)Nov 1, 2024
147 days to decisionK241646 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241646/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jun 7, 2024 |
| Decision date | Nov 1, 2024 |
| Days to decision | 147 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mvitro Co., Ltd. |
| Location | Seoul, KR |
| Contact | Jeong Seob Nam |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

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