

K160227 ACCENTO / HWA Dual/Single laserApr 22, 2016
84 days to decisionK160227 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160227/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jan 29, 2016 |
| Decision date | Apr 22, 2016 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bison Medical Co, Ltd. |
| Location | Guemcheon Gu, KR |
| Contact | SUN WOO LEE |
| 510(k) history | 3 submissions · 3 cleared · 2015-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160227/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026