

K190465 Evolve Breast PumpOct 18, 2019
234 days to decisionK190465 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190465/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Pump, Breast, Powered (HGX) |
| Date received | Feb 26, 2019 |
| Decision date | Oct 18, 2019 |
| Days to decision | 234 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Hygeia II Medical Group, Inc. |
| Location | Carlsbad, CA, US |
| Contact | Brett Nakfoor |
| 510(k) history | 4 submissions · 4 cleared · 2019-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190465/> 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 May 27, 2026