

K200406 Evolve Breast PumpMar 18, 2020
28 days to decisionK200406 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k200406/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Pump, Breast, Powered (HGX) |
| Date received | Feb 19, 2020 |
| Decision date | Mar 18, 2020 |
| Days to decision | 28 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/k200406/> 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