

**K193449 Electric Breast Pump (model KP033_01), Electric
Double Breast Pump (model KP053_01)**Sep 11, 2020
273 days to decisionK193449 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k193449/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Breast, Powered (HGX) |
| Date received | Dec 13, 2019 |
| Decision date | Sep 11, 2020 |
| Days to decision | 273 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Guangdong Horigen Mother & Baby Products Co., Ltd. |
| Location | Shantou, CN |
| Contact | Jun Deng |
| 510(k) history | 6 submissions · 6 cleared · 2016-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193449/> 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