

**K251754 Wearable Breast Pump (Model S33)**Sep 8, 2025  
91 days to decisionK251754 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k251754/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Pump, Breast, Powered (HGX)        |
| Date received         | Jun 9, 2025                        |
| Decision date         | Sep 8, 2025                        |
| Days to decision      | 91 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Shenzhen TPH Technology Co., Ltd.</b> |
| Location       | Shenzhen, CN                             |
| Contact        | Dale Wang                                |
| 510(k) history | 19 submissions · 19 cleared · 2022-2026  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251754/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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