

K253021 ANNE MaternalFeb 26, 2026
160 days to decisionK253021 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k253021/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received | Sep 19, 2025 |
| Decision date | Feb 26, 2026 |
| Days to decision | 160 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sibel Health, Inc. |
| Location | Chicago, IL, US |
| Contact | Kevin Dwyer |
| 510(k) history | 5 submissions · 5 cleared · 2023-2026 |

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