

K021115 GYNEFLEXDec 20, 2002
256 days to decisionK021115 · Product code: **HIR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k021115/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Perineometer (HIR) |
| Date received | Apr 8, 2002 |
| Decision date | Dec 20, 2002 |
| Days to decision | 256 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Naissance Holdings, LC |
| Location | Wahington, DC, US |
| Contact | NANCY E TAYLOR |
| 510(k) history | 1 submissions · 1 cleared · 2002-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021115/> 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 June 30, 2026