

**K974036 PATHWAY VAGINAL/RECTAL PERINEOMETER
PROBE**Dec 22, 1997
59 days to decisionK974036 · Product code: **HIR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k974036/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Perineometer (HIR) |
| Date received | Oct 24, 1997 |
| Decision date | Dec 22, 1997 |
| Days to decision | 59 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | The Prometheus Group |
| Location | Portsmouth, NH, US |
| Contact | RICHARD HORTON |
| 510(k) history | 11 submissions · 11 cleared · 1991-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974036/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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