

K970488 HYDROCHECK MICRO FILTERNov 4, 1997
267 days to decisionK970488 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k970488/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Breast, Powered (HGX) |
| Date received | Feb 10, 1997 |
| Decision date | Nov 4, 1997 |
| Days to decision | 267 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | White River Concepts |
| Location | San Clemente, CA, US |
| Contact | JACKIE DARK |
| 510(k) history | 3 submissions · 3 cleared · 1997-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970488/> 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 29, 2026