

K072264 FASTPACK HCG IMMUNOASSAYDec 6, 2007
113 days to decisionK072264 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k072264/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Aug 15, 2007 |
| Decision date | Dec 6, 2007 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Qualigen, Inc. |
| Location | Carlsbad, CA, US |
| Contact | MICHAEL S POIRIER |
| 510(k) history | 15 submissions · 15 cleared · 2000-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072264/> 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 19, 2026