

K172322 Atellica IM Total hCG (ThCG)Mar 29, 2018
240 days to decisionK172322 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k172322/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Aug 1, 2017 |
| Decision date | Mar 29, 2018 |
| Days to decision | 240 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Siemens Healthcare Diagnostics, Inc. |
| Location | New York, NY, US |
| Contact | Anoop Joy |
| Website | https://www.siemens-healthineers.com |
| 510(k) history | 152 submissions · 151 cleared · 2008-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172322/> 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 May 14, 2026