

**K072714 TINA-QUANT HEMOGLOBIN A1C GEN.2 TEST
SYSTEM**Apr 18, 2008
206 days to decisionK072714 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k072714/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Assay, Glycosylated Hemoglobin (LCP) |
| Date received | Sep 25, 2007 |
| Decision date | Apr 18, 2008 |
| Days to decision | 206 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics Corp. |
| Location | Indianapolis, IN, US |
| Contact | THERESA A BUSH |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072714/>; 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 9, 2026