

K072458 GBI TSH NEONATAL SCREENING KITApr 10, 2008
223 days to decisionK072458 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k072458/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Thyroid-stimulating Hormone (JLW) |
| Date received | Aug 31, 2007 |
| Decision date | Apr 10, 2008 |
| Days to decision | 223 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Golden Bridge International, Inc. |
| Location | Mukilteo, WA, US |
| Contact | XIAOPING ZHANG |
| 510(k) history | 1 submissions · 1 cleared · 2008-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072458/> 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 25, 2026