

**K060754 ELECSYS TSH CALSET W/MODELS 04738551**Apr 18, 2006  
28 days to decisionK060754 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k060754/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Calibrator, Secondary (JIT)        |
| Date received         | Mar 21, 2006                       |
| Decision date         | Apr 18, 2006                       |
| Days to decision      | 28 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostics Corp.</b>            |
| Location       | Indianapolis, IN, US                      |
| Contact        | KAY A TAYLOR                              |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060754/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026