

**K120591 DIAMOND TOKYO BOEKI ISE MODULE CALIBRATOR  
1,2,1-2**Apr 17, 2012  
49 days to decisionK120591 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k120591/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Calibrator, Secondary (JIT)        |
| Date received         | Feb 28, 2012                       |
| Decision date         | Apr 17, 2012                       |
| Days to decision      | 49 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Diamond Diagnostics, Inc.</b>        |
| Location       | Holliston, MA, US                       |
| Contact        | KATHY CRUZ                              |
| 510(k) history | 26 submissions · 26 cleared · 2001-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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