FDA 510(k) Premarket Notification

**CLEARED**

Apr 17, 2013
111 days to decision

# K124009 MISSION CLINICHECK ASSAYED CHEMISTRY CONTROLS, LEVEL 1, MISSION CLINICHECK ASSAYED CHEMISTRY CONTROLS LEVEL 2, MISSION C

K124009 · Product code: **JJY** · Chemistry
Source: https://www.510kdatabase.net/k124009/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Dec 27, 2012 |
| Decision date | Apr 17, 2013 |
| Days to decision | 111 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k124009/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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