

**K093032 TRIAGE TOTAL 3 CONTROLS AND CALIBRATION
VERIFICATION SET**

Nov 13, 2009
45 days to decision

K093032 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k093032/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Sep 29, 2009 |
| Decision date | Nov 13, 2009 |
| Days to decision | 45 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biosite Incorporated |
| Location | San Diego, CA, US |
| Contact | MARA CALER |
| 510(k) history | 46 submissions · 45 cleared · 1990-2010 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k093032/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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