

**K130157 AUDIT MICROCV BETA-HYDROXYBUTYRIC ACID
LINEARITY SET**Mar 19, 2013
55 days to decisionK130157 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k130157/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Jan 23, 2013 |
| Decision date | Mar 19, 2013 |
| Days to decision | 55 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Aalto Scientific, Ltd. |
| Location | Mchenry, IL, US |
| Contact | DESSI LYAKOV |
| 510(k) history | 35 submissions · 35 cleared · 1982-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130157/>; 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 1, 2026