

**K120615 ALERE CHOLESTECH LDX ANALYZER, ALERE  
CHOLESTECH LDX LIPID PROFILE - GLU CASSETTE**May 15, 2013  
441 days to decisionK120615 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k120615/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Glucose Oxidase, Glucose (CGA)     |
| Date received         | Feb 29, 2012                       |
| Decision date         | May 15, 2013                       |
| Days to decision      | 441 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Alere San Diego Inc. Db a Biosite,Innovacon,Hemosen</b> |
| Location       | San Deigo, CA, US  |
| Contact        | EDWARD BREHM, PH.D.  |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013                      |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120615/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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