

**K130870 HITACHI CLINICAL ANALYZER S TEST REAGENT  
CARTRIDGE CALCIUM (CA)**May 2, 2013  
34 days to decisionK130870 · Product code: **CIC** · Chemistry  
Source: <https://www.510kdatabase.net/k130870/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Cresolphthalein Complexone, Calcium (CIC) |
| Date received         | Mar 29, 2013                              |
| Decision date         | May 2, 2013                               |
| Days to decision      | 34 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Hitachi Chemical Diagnostics, Inc.</b> |
| Location       | Mountain View, CA, US                     |
| Contact        | ERIKA AMMIRATI                            |
| 510(k) history | 16 submissions · 16 cleared · 2003-2021   |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130870/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026