

**K171401 ELITech Clinical Systems BILIRUBIN TOTAL 4+1,  
ELITech Clinical Systems BILIRUBIN DIRECT 4+1**Jul 11, 2017  
60 days to decisionK171401 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k171401/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	May 12, 2017
Decision date	Jul 11, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Elitechgroup</b>
Location	Bothell, WA, US
Contact	Valerie Gourdon
510(k) history	17 submissions · 17 cleared · 2011-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171401/> 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 18, 2026