

**K050713 DUET HS-CRP LIT ASSAY, CATALOG NUMBER: 4010,  
DUET HS-CRP CALIBRATOR SET, CATALOG NUMBER: 4511**

Jun 6, 2005  
80 days to decision

K050713 · Product code: **DCN** · Chemistry  
Source: <https://www.510kdatabase.net/k050713/>

**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | System, Test, C-reactive Protein (DCN) |
| Date received         | Mar 18, 2005                           |
| Decision date         | Jun 6, 2005                            |
| Days to decision      | 80 days                                |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Good Biotech Corp.</b>             |
| Location       | Taichung, TW                          |
| Contact        | VICTOR CHIOU                          |
| 510(k) history | 8 submissions · 8 cleared · 2002-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k050713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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