

**K132167 I-CHROMA IFOB WITH I-CHROMA READER**May 2, 2014  
294 days to decisionK132167 · Product code: **OOX** · Hematology  
Source: <https://www.510kdatabase.net/k132167/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Automated Occult Blood Analyzer (OOX) |
| Date received         | Jul 12, 2013                          |
| Decision date         | May 2, 2014                           |
| Days to decision      | 294 days                              |
| Third-party review    | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Boditech Med, Inc.</b>             |
| Location       | Chuncheon-Si, Gang-Won-Do, KR         |
| Contact        | SANG YEOL PARK                        |
| 510(k) history | 2 submissions · 2 cleared · 2014-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132167/> 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 31, 2026