

**K123416 INSIGNIA WITH ITERO**Mar 13, 2013  
127 days to decisionK123416 · Product code: **DYW** · Dental  
Source: <https://www.510kdatabase.net/k123416/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Bracket, Plastic, Orthodontic (DYW) |
| Date received         | Nov 6, 2012                         |
| Decision date         | Mar 13, 2013                        |
| Days to decision      | 127 days                            |
| Third-party review    | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ormco Corp.</b>                      |
| Location       | Mchenry, IL, US                         |
| Contact        | Wendy Garman                            |
| 510(k) history | 40 submissions · 39 cleared · 1978-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123416/> 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 June 5, 2026