

**K030045 OLYMPUS CHOLINESTERASE REAGENT (CATALOG NUMBER OSR6114)**Feb 21, 2003  
46 days to decisionK030045 · Product code: **DIH** · Chemistry  
Source: <https://www.510kdatabase.net/k030045/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Colorimetry, Cholinesterase (DIH)  |
| Date received         | Jan 6, 2003                        |
| Decision date         | Feb 21, 2003                       |
| Days to decision      | 46 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Olympus America, Inc.</b>              |
| Location       | Lake Success, NY, US                      |
| Contact        | MICHAEL CAMPBELL                          |
| 510(k) history | 149 submissions · 149 cleared · 1994-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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