

**K040761 AXSYM CYCLOSPORINE**Apr 30, 2004  
36 days to decisionK040761 · Product code: **MKW** · Chemistry  
Source: <https://www.510kdatabase.net/k040761/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Cyclosporine (MKW)                 |
| Date received         | Mar 25, 2004                       |
| Decision date         | Apr 30, 2004                       |
| Days to decision      | 36 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Abbott Laboratories, Inc.</b>      |
| Location       | Abbott Park, IL, US                   |
| Contact        | GRACE LEMIEUX                         |
| 510(k) history | 6 submissions · 6 cleared · 2002-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040761/> 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 25, 2026