

**K030832 PRIMOSPLINT SYSTEM**Sep 17, 2003  
184 days to decisionK030832 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k030832/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mouthguard, Prescription (MQC)     |
| Date received         | Mar 17, 2003                       |
| Decision date         | Sep 17, 2003                       |
| Days to decision      | 184 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cosmedent, Inc.</b>                  |
| Location       | Chicago, IL, US                         |
| Contact        | MICHAEL O'MALLEY                        |
| 510(k) history | 28 submissions · 28 cleared · 1986-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030832/> 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 July 1, 2026