

**K022809 EZ SPLINT & EZ SPLINT PM**Oct 17, 2003  
420 days to decisionK022809 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k022809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Aug 23, 2002
Decision date	Oct 17, 2003
Days to decision	420 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Power Products, Inc.-Splintek</b>
Location	Great Neck, NY, US
Contact	CAROLANN KOTULA
510(k) history	3 submissions · 3 cleared · 2003-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k022809/> 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 21, 2026