

K100545 SLEEPRIGHTJun 4, 2010
98 days to decisionK100545 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k100545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Feb 26, 2010
Decision date	Jun 4, 2010
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Power Products, Inc.-Splintek
Location	Great Neck, NY, US
Contact	MELAINE HASEK
510(k) history	3 submissions · 3 cleared · 2003-2010

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