

K063483 DEN TEK NIGHTGUARDJan 23, 2007
67 days to decisionK063483 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k063483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Nov 17, 2006
Decision date	Jan 23, 2007
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Den Tek Oral Care, Inc.
Location	Washington, Dc, DC, US
Contact	Jeffrey Shapiro
510(k) history	8 submissions · 8 cleared · 2007-2015

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