

K981546 NTI CLENCHING SUPPRESSION SYSTEMJul 15, 1998
76 days to decisionK981546 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k981546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Apr 30, 1998
Decision date	Jul 15, 1998
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Heraeus Kulzer, Inc.
Location	Elkhart, IN, US
Contact	CHERYL V ZIMMERMAN
510(k) history	145 submissions · 145 cleared · 1988-2009

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