

**K965205 TEFGEN - LS**Apr 30, 1997  
125 days to decisionK965205 · Product code: **NPK** · Dental  
Source: <https://www.510kdatabase.net/k965205/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	Dec 26, 1996
Decision date	Apr 30, 1997
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Custom Medical, Inc.</b>
Location	Lubbock, TX, US
Contact	BRUCE G RUEFER
510(k) history	5 submissions · 5 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965205/> 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 2, 2026