

K935137 TEFGEN-FDAug 15, 1994
291 days to decisionK935137 · Product code: **NPK** · Dental
Source: <https://www.510kdatabase.net/k935137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	Oct 28, 1993
Decision date	Aug 15, 1994
Days to decision	291 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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