

K945200 FIXODENT, FIXODENT FRESH, FASTEETH AND EXTRA HOLD FASTEETH DENTURE ADHESIVCESNov 30, 1994
36 days to decisionK945200 · Product code: **KOO** · Dental
Source: <https://www.510kdatabase.net/k945200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Denture, Polyvinyl Methylether Maleic Acid Calcium-sodium Double Salt (KOO)
Date received	Oct 25, 1994
Decision date	Nov 30, 1994
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Procter & Gamble Co.
Location	Cincinnati, OH, US
Contact	RANDALL A STOLT
Website	http://www.pg.com/
510(k) history	23 submissions · 23 cleared · 1988-2014

Procter & Gamble Co. is a consumer health and personal care company headquartered in Cincinnati, US. The company develops and markets a broad range of health and wellness products globally. Procter & Gamble has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus has centered on Obstetrics & Gynecology devices, which represent the dominant category of its submissions. FDA 510(k) clearances span from 1988 to 2014, establishing a historical regulatory record in feminine care and oral health device categories.

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