FDA 510(k) Premarket Notification

K955740 GLUFLORMA

CLEARED

Feb 8, 1996
55 days to decision

K955740 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k955740/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Dec 15, 1995
Decision date	Feb 8, 1996
Days to decision	55 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Midwest Orthodontic Mfg.**
Location	Chicago, IL, US
Contact	JEFFERY L FASNACHT
510(k) history	7 submissions · 7 cleared · 1990-1998