FDA 510(k) Premarket Notification

K982537 TOKUYAMA SOFRELINER

CLEARED

Aug 24, 1998
34 days to decision

K982537 · Product code: **EBI** · Dental
Source: https://www.510kdatabase.net/k982537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Jul 21, 1998
Decision date	Aug 24, 1998
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tokuyama America, Inc.**
Location	Washington, DC, US
Contact	DANIEL J MANELLI
510(k) history	22 submissions · 22 cleared · 1990-2002