FDA 510(k) Premarket Notification

K213765 Glidewell 3DP Denture Base Resin

CLEARED

Jun 22, 2022
203 days to decision

K213765 · Product code: **EBI** · Dental
Source: https://www.510kdatabase.net/k213765/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Dec 1, 2021
Decision date	Jun 22, 2022
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Prismatik Dentalcraft, Inc.**
Location	Newport Beach, CA, US
Contact	Jiahe Li
510(k) history	57 submissions · 57 cleared · 2010-2026