FDA 510(k) Premarket Notification

K230115 Denture Base Resin

CLEARED

Mar 17, 2023
59 days to decision

K230115 · Product code: **EBI** · Dental
Source: https://www.510kdatabase.net/k230115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Jan 17, 2023
Decision date	Mar 17, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aidite (Qinhuangdao) Technology Co., Ltd.**
Location	Qinhuangdao, CN
Contact	Chen Yingying
510(k) history	16 submissions · 16 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Icas Group**
Contact	Julie Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov