FDA 510(k) Premarket Notification

K203712 The Slide

CLEARED

Jul 20, 2021
211 days to decision

K203712 · Product code: **LQZ** · Dental
Source: https://www.510kdatabase.net/k203712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Jaw Repositioning (LQZ)
Date received	Dec 21, 2020
Decision date	Jul 20, 2021
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biotex, Inc.**
Location	Houston, TX, US
Contact	Wade Munsch
510(k) history	10 submissions · 10 cleared · 2006-2024