FDA 510(k) Premarket Notification

K211978 Jplant

CLEARED

Jan 5, 2022
194 days to decision

K211978 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k211978/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 25, 2021
Decision date	Jan 5, 2022
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jj Medical Co., Ltd.**
Location	Seoul, KR
Contact	Sun Jae Lee
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

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