FDA 510(k) Premarket Notification

CLEARED

K202046 LOTA SLA Dental Implant System and LOTA HA Dental Implant System

Mar 1, 2022
586 days to decision

K202046 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k202046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 23, 2020
Decision date	Mar 1, 2022
Days to decision	586 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kj Meditech Co., Ltd.**
Location	Fullerton, CA, US
Contact	Hyukki Moon
510(k) history	12 submissions · 12 cleared · 2011-2022

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