FDA 510(k) Premarket Notification

K202039 Honorst Implant System

CLEARED

Sep 25, 2020
64 days to decision

K202039 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k202039/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 23, 2020
Decision date	Sep 25, 2020
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medimecca Co., Ltd.**
Location	Anaheim, CA, US
Contact	Seung Yoon Lee
510(k) history	4 submissions · 4 cleared · 2013-2020

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