FDA 510(k) Premarket Notification

K221752 Stella

CLEARED

Jun 4, 2023
353 days to decision

K221752 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k221752/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 16, 2022
Decision date	Jun 4, 2023
Days to decision	353 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shinhung Mst Co., Ltd.**
Location	Wonju-Si, KR
Contact	Sun Ho Lee
510(k) history	7 submissions · 7 cleared · 2013-2023