FDA 510(k) Premarket Notification

K223518 iOrtho

CLEARED

Jun 13, 2023
202 days to decision

K223518 · Product code: **PNN** · Dental
Source: https://www.510kdatabase.net/k223518/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Nov 23, 2022
Decision date	Jun 13, 2023
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai EA Medical Instruments Co., Ltd.**
Location	Wuxi, CN
Contact	Jessica Luo
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Breanne Butler

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