FDA 510(k) Premarket Notification

K202691 Ortholock Anchorage Devices

CLEARED

Apr 28, 2022
590 days to decision

K202691 · Product code: **OAT** · Dental
Source: https://www.510kdatabase.net/k202691/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Sep 15, 2020
Decision date	Apr 28, 2022
Days to decision	590 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Craniofacial Technologies, Inc.**
Location	Bell Canyon, CA, US
Contact	Kevin Kaveh
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Nilo Medical Consulting Group**
Contact	Michael Nilo

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