FDA 510(k) Premarket Notification

K211427 CREOKORREKT Aligners

CLEARED

Oct 13, 2022
524 days to decision

K211427 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k211427/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 7, 2021
Decision date	Oct 13, 2022
Days to decision	524 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Creodent Prosthetics, Ltd.**
Location	New York, NY, US
Contact	Calvin Shim
510(k) history	9 submissions · 9 cleared · 2013-2022

REGULATORY CONSULTANT

Consulting firm	**Withus Group, Inc.**
Contact	April Lee

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