FDA 510(k) Premarket Notification

CLEARED

K212803 DailyMate Orthodontic Aligner System

May 23, 2022
263 days to decision

K212803 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k212803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 2, 2021
Decision date	May 23, 2022
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3D Global Biotech, Inc.**
Location	New Taipei City 221, TW
Contact	Keng-Liang Ou
510(k) history	2 submissions · 2 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	**Duocare, LLC**
Contact	Diana Lam

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