FDA 510(k) Premarket Notification

CLEARED

K230592 LuxCreo Dental Night Guard Resin

Jan 18, 2024
321 days to decision

K230592 · Product code: **MQC** · Dental
Source: https://www.510kdatabase.net/k230592/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Mar 3, 2023
Decision date	Jan 18, 2024
Days to decision	321 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**LuxCreo, Inc.**
Location	Belmont, CA, US
Contact	Mike Yang
510(k) history	4 submissions · 4 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.**
Contact	Reanny Wang

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230592/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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