FDA 510(k) Premarket Notification

K191033 LunaGuard Nighttime Dental Protector

CLEARED

Aug 5, 2019
109 days to decision

K191033 · Product code: **OBR** · Dental
Source: https://www.510kdatabase.net/k191033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Apr 18, 2019
Decision date	Aug 5, 2019
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mckeon Products**
Location	Warren, MI, US
Contact	Devin Benner
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Right Submission, LLC**
Contact	Elizabeth FitzGerald

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