FDA 510(k) Premarket Notification

K190339 Helioseal F Plus

CLEARED

Jul 29, 2019
165 days to decision

K190339 · Product code: **EBC** · Dental
Source: https://www.510kdatabase.net/k190339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Feb 14, 2019
Decision date	Jul 29, 2019
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ivoclar Vivadent, AG**
Location	Amherst, NY, US
Contact	Sandra Cakebread
510(k) history	31 submissions · 31 cleared · 2004-2022

REGULATORY CONSULTANT

Consulting firm	**Ivoclar Vivadent, Inc.**
Contact	Lori Aleshin

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