

K190339 Helioseal F PlusJul 29, 2019
165 days to decisionK190339 · 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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190339/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026