

K254245 ZAFIRA®

Mar 3, 2026
64 days to decision

K254245 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k254245/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 29, 2025
Decision date	Mar 3, 2026
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	New Stetic, SA
Location	Guarne, CO
Contact	Juan David Jaramillo Gomez
Website	https://www.newstetic.com
510(k) history	2 submissions · 2 cleared · 2019-2026

New Stetic, SA offers comprehensive dental and surgical healthcare solutions. The company operates with a manufacturing facility in Guarne, CO, and serves a global market across 64 countries. The company has received FDA 510(k) clearances from total submissions. Dental devices represent 100% of its regulatory submissions. New Stetic’s FDA 510(k) clearance history spans from 2019 to 2026, demonstrating continued regulatory activity and market engagement. The company’s cleared device portfolio includes CAD/CAM disc systems and specialized dental products. These devices supp...

REGULATORY CONSULTANT

Consulting firm	Aclivi, LLC
Contact	Chris Brown

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