March 3, 2026

New Stetic, SA
℅ Chris Brown
Manager
Aclivi, LLC
405 Tropics Ave.
Daytona Beach, Florida 32124

Re: K254245
Trade/Device Name: Zafira®
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: February 25, 2026
Received: February 26, 2026

Dear Chris Brown:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K254245

Device Name
ZAFIRA®

Indications for Use *(Describe)*
ZAFIRA® is indicated as a direct and indirect restorative material.

ZAFIRA® Light Curing Composite is intended for:
- Posterior restorations (Class I and II)
- Anterior restorations (Class III and IV)
- Cervical restorations (Class V)
- Restoration of deciduous teeth
- Direct veneers
- Indirect restorations (inlays, onlays, and veneers)

ZAFIRA® Light Curing Gum Composite is intended for reproduction of gingiva in prosthetic restorations including:
- Implant restorations
- Crowns and bridges
- Full or partial prostheses

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K254245

510(k) Summary
ZAFIRA®
December 29, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name: New Stetic S.A.
Carrera 53 No. 50 – 09
Guarne - Antioquia, Colombia
Telephone: +57 604 550 00 00
Fax: n/a

Official Contact: Juan David Jaramillo Gomez, General Manager
Email: infocolombia@newstetic.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	ZAFIRA®
Common Name:	Material, tooth shade, resin
Regulation Name:	Tooth Shade Resin Material
Regulation Number:	21 CFR 872.3690
Device Class:	Class II
Product Code:	EBF
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and technological characteristics to the following Predicate device. The Subject device shares technological characteristics with the following Reference devices.

510(k)	Predicate Device Name	Company Name
K183380	Tetric® PowerFill	Ivoclar Vivadent, AG
510(k)	**Reference Device Name**	**Company Name**
K183476	3M Filtek Universal Restorative	3M ESPE Dental Products
K153325	GRADIA PLUS	GC AMERICA INC.
K231389	Harvest Dental HD Gum Strip	Harvest Dental Products, LLC.

INDICATIONS FOR USE

ZAFIRA® is indicated as a direct and indirect restorative material.

ZAFIRA® Light Curing Composite is intended for:
- Posterior restorations (Class I and II)
- Anterior restorations (Class III and IV)
- Cervical restorations (Class V)
- Restoration of deciduous teeth
- Direct veneers
- Indirect restorations (inlays, onlays, and veneers)

ZAFIRA® Light Curing Gum Composite is intended for reproduction of gingiva in prosthetic restorations including:
- Implant restorations
- Crowns and bridges
- Full or partial prostheses

DEVICE DESCRIPTION

The Subject device is a viscous solution consisting of methacrylate-based resin, silane agent, filler, photo initiators and pigment stored in a 4.2-gram polypropylene syringe.

The Subject device is used by a dental professional (dentist or dental technician) for the restoration of anterior and posterior teeth and for the reconstruction of individual gum areas either directly in the mouth or during the characterization of indirectly fabricated dental prostheses. The device is not intended to be in contact with dental pulp. Device labeling provides guidance on isolation from pulp.

There are two sub-models of the Subject device ZAFIRA® Light Curing Composite and ZAFIRA® Light Curing Gum Composite.

The Subject device is available in:

- 16 tooth shade colors – (ZAFIRA® Light Curing Composite)
  A1, A2, A3, B1, BL and BLX (both Dentin and Enamel shades)
  A3.5 (Dentin), B2 (Enamel), Incisal, Opaquer
- 5 gingival/gum shade colors (ZAFIRA® Light Curing Gum Composite)
  Brown, Dark Pink Veined, Dark Pink, Light Pink, and Orange Pink

Dental restorations fabricated using the Subject device are one-time use, prescription-only devices.

Methacrylates are known materials, commonly used in the dental industry for fixed and removable prosthetic devices due to their physical-chemical, mechanical, and biocompatible properties.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

Material property testing to ISO 4049. Accelerated shelf-life stability testing according to the sponsor's protocol.

Biocompatibility testing performed for the Subject device:

- Cytotoxicity testing to ISO 10993-5
- Sensitization testing to ISO 10993-10
- Irritation testing to ISO 10993-23

The Subject device is comprised of methacrylate resin materials and pigments which do not contain any metal and the device is not used with any metal materials. The material is electrically nonconductive, nonmetallic, and nonmagnetic so no MRI safety testing was performed.

No clinical or animal testing data is included in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent in Indications for Use, Technological Characteristics, and design principles to Predicate device listed above and additionally incorporates technology of the Reference devices. The Summary tables at the end of this section compare the Subject, Predicate and the Reference devices.

Indications for Use

The Indications for Use Statement (IFUS) of the Subject device is similar to the K183380 Predicate device. Use of the Subject device is not intended for all the indications presented in the Predicate device, nor tied to specific curing lights, so these are not mentioned in the Subject device IFUS. The Subject and Predicate devices share Class I, Class II, Class V and restoration of deciduous teeth indications. The IFUSs of the Reference devices are leveraged for the additional indications of the Subject device. K183476 is leveraged for anterior restorations and indirect restorations including inlays, onlays and

veneers. K153325 is leveraged for indirect restoration and reproduction of gum tissue. K231389 is leveraged for gum tissue reproduction for crown, bridges and removable restorations.

Minor differences in wording used to describe the restoration types or references to specific curing lights do not impact substantial equivalence because the IFUSs express the same intended use in dental prosthetic restorations.

Technological Characteristics
The Subject, K183380 Predicate, K183476 Reference and K153325 Reference devices have the same product code/regulation and are light cured after being dispensed from a re-usable syringe. The K231389 includes the same product code as the Subject device, but as a Secondary product code. The Subject, Predicate and Reference devices are all light cured methacrylate-based restorative materials. The Subject, Predicate and Reference devices are all single-use, Rx Only devices, that are supplied and used non-sterile. The Subject, Predicate and Reference devices have all demonstrated biocompatibility according to the testing requirements of ISO 10993-1.

K183380 Tetric® PowerFill
The K183380 Predicate device shares the same intended use for Class I, Class II and Class V restorations and restoration of deciduous teeth. While the Predicate device is not specifically indicated for anterior restorations, it does not impact substantial equivalence as Reference devices are leveraged for the additional intended uses. Both the Subject and K183380 Predicate devices are intended for usage on occlusal surfaces and have been tested to ISO 4049 meeting the acceptance criteria of the standard.

K183476 3M Filtek Universal Restorative
The K183476 Reference device shares the same intended use for anterior and posterior restorations including occlusal surfaces as well as indirect restorations including inlays, onlays and veneers. While the K183476 Reference device is not indicated for cervical restorations, it does not impact substantial equivalence as the Predicate and other Reference devices are leveraged for additional intended uses. Both the Subject and K183476 Reference devices have been tested to ISO 4049 meeting the acceptance criteria of the standard.

K153325 GRADIA PLUS
The K153325 Reference device shares the same intended use for inlays, onlays and veneers and reproduction of gum tissues for crown restorations. While the K153325 Reference device is not indicated for cervical restorations or direct restorations, it does not impact substantial equivalence as the Predicate and other Reference devices are leveraged for additional intended uses. While the K153325 Reference device was tested to ISO 10477, the Subject device was tested to and met the acceptance criteria of ISO 4049, which has more stringent acceptance criteria, mitigating this difference.

K231389 Harvest Dental HD Gum Strip
The K231389 Reference device shares the same intended use for reproduction of gum tissues for crown and bridge and removable restorations. While the K231389 Reference device is not indicated for tooth surfaces of direct and indirect restorations, it does not impact substantial equivalence as the Predicate and other Reference devices are leveraged for additional intended uses. While the K231389 Reference device was tested to ISO 10477, the Subject device was tested to and met the acceptance criteria of ISO 4049, which has more stringent acceptance criteria, mitigating this difference. The nature of how the Subject and K231389 Reference device materials are applied to the restorations differs. However, the method of application does not impact the intended use of the device. Furthermore, both devices are light cured having the same method of action.

CONCLUSION
Minor differences in specific location of use stated in an Indication for Use Statement do not change the intended use of composite material being used in the restoration of teeth. The Subject device has been tested to ISO 4049, meeting the requirements of the standard, mitigating slight differences in individual locations of use of the Predicate and Reference devices.

Overall, the Indications for Use statements are similar, with the Indications for Use of the Subject device encompassed within the Indications for Use of the Predicate and Reference devices.

Overall, the Technological Characteristics, mode of operation, materials and usage of the Subject device are highly similar to that of the Predicate and Reference devices.

Overall, the Subject device is substantially equivalent to the Predicate and Reference devices. The basis for that belief is summarized in the following comparison tables.

Table A – Comparison of Indications for Use Statement

Subject Device ZAFIRA® New Stetic, SA	**Predicate Device** Tetric® PowerFill Ivoclar Vivadent, AG K183380	**Reference Device** 3M Filtek Universal Restorative 3M ESPE Dental Products K183476	**Reference Device** GRADIA PLUS GC America Inc. K153325	**Reference Device** Harvest Dental HD Gum Strip Harvest Dental Products, LLC K231389
ZAFIRA® is indicated as a direct and indirect restorative material. *ZAFIRA® Light Curing Composite is intended for:* *- Posterior restorations (Class I and II)* *- Anterior restorations (Class III and IV)* *- Cervical restorations (Class V)* *- Restoration of deciduous teeth* *- Direct veneers* *- Indirect restorations (inlays, onlays, and veneers)* *ZAFIRA® Light Curing Gum Composite is intended for reproduction of gingiva in prosthetic restorations including:* *- Implant restorations* *- Crowns and bridges* *- Full or partial prostheses*	*Conventional application (Light intensity ≤ 2,000 mW/cm2):* *- Restorations in the posterior region (Class I and II, including the replacement of individual cusps)* *- Class V restorations (cervical caries, root erosion, wedge-shaped defects)* *- Reconstructive build-ups* *- Restoration of deciduous teeth* *Light-curing using the 3sCure mode of Bluephase® PowerCure (Light Intensity 3,050 mW/cm2):* *- Restorations in the posterior region of permanent dentition (Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect*	*• Direct anterior and posterior restorations (including occlusal surfaces)* *• Core build-ups* *• Splinting* *• Indirect restorations including inlays, onlays and veneers*	*1. Crown and Bridgework (with metal backing)* *2. Metal free restorations: Jacket Crowns, Inlays, Onlays and Laminated Veneers* *3. Implant superstructures* *4. Reproduction of gum tissue for crown restorations*	*Harvest Dental HD Gum Strip is indicated for adding texture, form and color to the gingival area of a dental prosthesis which includes crowns, bridges and full and partial prostheses. This composite strip is bondable to polymethylmethacrylate (PMMA), metals and ceramics (zirconia).*

Table B - Comparison of Technological Characteristics

Topic	**Subject Device** ZAFIRA® New Stetic, SA	**Predicate Device** Tetric® PowerFill Ivoclar Vivadent, AG K183380	**Reference Device** 3M Filtek Universal Restorative 3M ESPE Dental Products K183476	**Reference Device** GRADIA PLUS GC America Inc. K153325	**Reference Device** Harvest Dental HD Gum Strip Harvest Dental Products, LLC K231389
Reason for Predicate/Reference	Not Applicable	Material type, indications for use, usage location, how used	Material type, indications for use, usage location, how used	Material type, indications for use, usage location, how used	Specific use in reproduction of gingiva in restorations
Intended Use	Light-cured composite resin for the direct or indirect restoration of anterior and posterior teeth and for the reconstruction of individual gum areas.	Light-cured composite resin for the direct restoration of posterior and deciduous teeth and reconstructive build-ups.	Light-cured composite resin for the direct or indirect restoration of anterior and posterior teeth and for the reconstructive build-ups.	Light-cured composite resin for the direct or indirect restoration of anterior and posterior teeth and for the reconstruction of individual gum areas	Light-cured composite resin to reproduce natural gingival form, texture, and color on removable or fixed prosthetic bases.
Product Code	EBF	EBF	EBF	EBF	EBI, EBF
Regulation	872.3690	872.3690	872.3690	872.3690	872.3760
Material Type	Light cured methacrylate-based composite resin	Light cured methacrylate-based composite resin	Light cured methacrylate-based composite resin	Light cured methacrylate-based composite resin	Light cured methacrylate-based composite resin
How Used	Dispense from re-usable syringe then light cure	Dispense from re-usable syringe then light cure	Dispense from re-usable syringe then light cure Dispense from single-use capsule then light cure	Dispense from re-usable syringe then light cure	Individual strip, apply, then light cure
Usage Location	ZAFIRA® Light Curing Composite: - Posterior restorations (Class I and II) - Anterior restorations (Class III and IV) - Cervical restorations (Class V) - Restoration of deciduous teeth - Direct veneers - Indirect restorations (inlays, onlays, and veneers)	- Posterior restorations (Class I and II, including the replacement of individual cusps) - Cervical restorations (Class V restorations) - Reconstructive build-ups - Restoration of deciduous teeth	- Direct anterior and posterior restorations (including occlusal surfaces) - Core build-ups - Splinting - Indirect restorations including inlays, onlays and veneers	- Crown and Bridgework (with metal backing) - Jacket Crowns, Inlays, Onlays and Laminated Veneers - Implant superstructures	n/a
	ZAFIRA® Light Curing Gum Composite - Implant restorations - Crowns and bridges - Full or partial prostheses	n/a	n/a	- Implant superstructures - Crown restorations	- Crowns - Bridges - Full and partial prostheses
Occlusal surfaces	Yes	Yes	Yes	Yes	n/a
Performance Testing	ISO 4049	ISO 4049	ISO 4049	ISO 10477	ISO 10477
Biocompatibility Testing	Cytotoxicity – ISO 10993-5 Sensitization – ISO 10993-10 Irritation – ISO 10993-23	Cytotoxicity – ISO 10993-5 Genotoxicity – ISO 10993-3	Cytotoxicity – ISO 10993-5 Genotoxicity – ISO 10993-3 Implantation – ISO 10993-6 Sensitization – ISO 10993-10 Systemic Toxicity – ISO 10993-11	Not defined	Cytotoxicity – ISO 10993-5 Sensitization – ISO 10993-10 Oral Mucosa Irritation – ISO 10993-23
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Prescription	Rx only	Rx only	Rx only	Rx only	Rx only
Usage	Single use	Single use	Single use	Single use	Single use