July 1, 2026

Ivoclar Vivadent, Inc.
Anderjeet Gulati
Sr. Manager of QA & Regulatory Affairs
175 Pineview Dr.
Amherst, New York 14228

Re: K261485
Trade/Device Name: Tetric plus Fill;Tetric plus Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: May 5, 2026
Received: May 5, 2026

Dear Anderjeet Gulati:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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)*
K261485

Device Name
Tetric plus Fill;
Tetric plus Flow

Indications for Use *(Describe)*

Tetric plus Fill:
– Missing tooth structure in anterior and posterior teeth

Types of restorations:
– Restorations of all types of permanent dentition (including the replacement of individual cusps in the posterior region)
– Reconstructive build-ups
– Restorations of deciduous teeth
– Repair of composite / ceramic restorations
– Direct veneers
– Sealing of implant screw channels

Tetric plus Flow:
– Missing tooth structure in anterior and posterior teeth

Types of restorations:
– Initial layer up to 4 mm in Class I and II restorations*
– Small direct restorations in permanent teeth (not occlusion-bearing)*
– Restorations of deciduous teeth
– Liner under direct restorations of all cavity classes
– Class V restorations
– Extended fissure sealings
– Repair of composite / ceramic restorations
– Sealing of implant screw channels

*In case of occlusion-bearing restorations, apply a final layer using a sculptable composite material.

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.

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510(K) SUMMARY

Contact: Anderjeet Gulati, Sr. Manager QA & Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228
716-264-2046
Anderjeet.gulati@ivoclar.com

Company: Ivoclar Vivadent, AG
Bendererstrasse 2, Schaan, FL-9494, Liechtenstein
+423-235-3535

Date Prepared: May 5, 2026

Proprietary Name: **Tetric® plus Fill**
Tetric® plus Flow

Classification Name: Material, Tooth Shade, Resin (872.3790)
(Classification Code EBF)

Common Name: Dental Composite

Tetric plus Fill Predicate Device: Tetric PowerFill (K183380) by Ivoclar Vivadent AG, Liechtenstein

Tetric plus Flow Predicate Device: Tetric PowerFill (K183380) by Ivoclar Vivadent AG, Liechtenstein

Device Description:

Tetric® plus Fill is a light-curing, radiopaque composite resin for the direct restorative treatment of anterior and posterior teeth and for restoring occlusal surfaces.

Tetric® plus Flow is a flowable, light-curing, radiopaque composite resin for the direct restorative treatment of anterior and posterior teeth and for restoring occlusal surfaces.

In both, the principles of operation are the same. The dental professional starts with determining tooth shade, preparing the cavity, ensuring isolation, placing the matrix, lining the cavity close to the pulp, conditioning the cavity, applying the composite, and finishing/occlusion control/polishing.

Indications for Use:

Tetric plus Fill

-Missing tooth structure in anterior and posterior teeth

Types of restorations:
-Restorations of all types of permanent dentition (including the replacement of individual cusps in the posterior region)
-Reconstructive build-ups
-Restorations of deciduous teeth
-Repair of composite / ceramic restorations
-Direct veneers
-Sealing of implant screw channels

Tetric plus Flow

-Missing tooth structure in anterior and posterior teeth

Types of restorations:
-Initial layer up to 4mm in Class 1 and II restorations*
-Small direct restorations in permanent teeth (not occlusion-bearing)*
-restorations of deciduous teeth
-Liner under direct restorations of all cavity classes
-Class V restorations
-Extended fissure sealings
-Repair of composite / Ceramic restorations
-Sealing of implant screw channels

*In case of occlusion-bearing restorations, apply a final layer using a sculptable composite material.

Comparison to Predicate:

The primary predicate device to which Tetric plus Fill has been compared is Ivoclar Vivadent AG's Tetric PowerFill (K183380). See Comparison Matrix 1.

The primary predicate device to which Tetric plus Flow has been compared is Ivoclar Vivadent AG's Tetric PowerFill (K183380). See Comparison Matrix 2.

Comparison Matrix 1:

	Predicate Device:	Proposed Device:	Deviation	
Device	**Ivoclar Vivadent AG: Tetric PowerFill (K183380)**	**Ivoclar Vivadent AG: Tetric plus Fill**	**Yes**	**No**
Indications for Use	**Conventional application (Light intensity 2,000mW/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	**Indications** – Missing tooth structure in anterior and posterior teeth Types of restorations: – Restorations of all types of permanent dentition (including the replacement of individual cusps in the posterior region) – Reconstructive build-ups – Restorations of deciduous teeth – Repair of composite / ceramic restorations – Direct veneers – Sealing of implant screw channels	☒	☐
Precaution Measures/ Contraindications / Processing restrictions/ Side effects	**Contraindications**: - If a dry working field cannot be established, or the stipulated working technique cannot be applied - If a patient is known to be allergic to any of the ingredients of Tetric PowerFill	**Contraindications:** The use of this product is contraindicated if the patient is known to be allergic to any of its ingredients	☒	☐
Summary of Indications, Precaution Measures/ Contraindications / Processing restrictions/ Side effects	Tetric PowerFill and the new device Tetric plus Fill are both dental filling materials used by the dentist for the direct filling therapy in dentistry. The new device Tetric plus Fill can also be used for restoration in anterior teeth compared to the predicate. The indications of the new device Tetric plus Fill cover the indications of Tetric PowerFill for posterior teeth. In addition, Tetric plus Fill can also be used for direct veneers, for the repair of composite/ceramic restorations and the closure of implant screw channels. The application of the 3sCure mode of Bluephase PowerCure is described in the instructions for use for the new device under section “Applying the composite resin”. The contraindications are basically the same for both devices. The information regarding the dry working field can be found in section “Limitations of use” for the new device.			
Working Principle	Tetric PowerFill is a dental composite material for the use of direct filling in teeth.	Tetric plus Fill is a dental composite material for the use of direct filling in teeth.	☐	☒
Summary of Working Principle	No difference			
Delivery forms/dosage	Tetric PowerFill is available as syringes and cavifills in 3 different shades (IVA, IVB, IVW)	Tetric plus Fill is available as syringes and cavifills in 4 different shades (A2 plus, A3 plus, A3.5 plus, Bleach plus)	☒	☐
Summary of Delivery forms/dosage	Tetric plus Fill is available in 4 different shades with which all classical vita shades can be covered (see table below). This innovation can be achieved due to Tetric plus Fill`s advanced chameleon effect. This chameleon effect is enabled due to an adapted recipe (see section chemical composition) compared to the predicate device.			
Storage Conditions	48 months at 2-28 °C / 36-82 °F	48 months at 2-28 °C / 36-82 °F	☐	☒

Shade correspondence				
Tetric® plus	A2 plus	A3 plus	A3.5 plus	Bleach plus
VITA* classical shades	A1, A2, B2, C1, D2	A3, C2, C3, D3, D4	A3.5, A4, B3, B4, C4	B1, Bleach

* No registered trademark of Ivoclar.

Summary of Storage Conditions	No difference.			
Principles of Operation	**Step-by-step:** - Shade determination - Isolation - Cavity preparation - Pulp protection/Base (3sCure mode is mentioned) - Apply matrix/interdental wedge - Conditioning/Application of the bonding agent - Application of Tetric PowerFill - Finishing/Checking the occlusion/Finishing	**Step-by-step:** - Determining the tooth shade - Preparing the cavity to the principles of the adhesive technique - Ensuring isolation - Placing the matrix - Lining the cavity close to the pulp - Conditioning the cavity - Applying the composite - Finishing/Occlusion control/Polishing	☐	☒
Summary Principles of operation	No difference – The principle of operation is the same for both devices.			
Summary of Chemical Composition	The main ingredients used for the predicate device Tetric PowerFill have also been used for the new device Tetric plus Fill. To achieve the advantage of the chameleon-effect, new ingredients have been used in the recipe of Tetric plus Fill. The biocompatibility has been thoroughly assessed for the new device Tetric plus Fill. This is shown in the Biological Evaluation Report for Tetric plus Fill (OTCS-Doc-ID 36406884).			
Finished Device Specification	Applicable Standards: *ISO 4049:2019 – Dentistry – Polymer-based restorative materials*	Applicable Standards: *ISO 4049:2019 – Dentistry – Polymer-based restorative materials*	☐	☒
	Applicable FDA Guidance: *Dental Composite Resin Devices – Premarket Notification [510(k) Submission]*	*Applicable FDA Guidance:* *Dental Composite Resin Devices – Premarket Notification [510(k) Submission]*	☐	☒
Summary of Finished Device Specification	Both products fulfill the requirements of ISO 4049:2019 and the FDA Guidance “Composite Resin Devices”. Values for the new device are shown in the documents “Design Verification Matrix” (see OTCS-Doc-ID: 247717871 and LL252535447). The requirement depth of cure out of ISO 4049:2019 is ≥ 1.5 mm. Therefore, the Vickers hardness out of ISO 10477:2020 is considered to be the appropriate testing method to confirm higher claimed values. The differences in sensitivity to ambient light and radiopacity are not considered to be significantly different, as the requirements out of the relevant ISO are met.			
Sterilization	Not applicable. No sterilization recommendation.	Not applicable. No sterilization recommendation.	☐	☒
Single use	Consumable material	Consumable material	☐	☒
Summary of Performance Specification	The device performance is tested according to ISO 4049 and the FDA Guidance “Dental Composite Resin Devices” and is substantially equivalent for the new device compared to its predicate.			

Comparison Matrix 2:

	Predicate Device:	**Proposed Device:**	**Deviation**	
Device	**Ivoclar Vivadent AG: Tetric PowerFill Fill (K183380)**	**Ivoclar Vivadent AG: Tetric plus Flow**	**Yes**	**No**
Indications for Use	**Indications** **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	**Indications** – Missing tooth structure in anterior and posterior teeth Types of restorations: – Initial layer up to 4 mm in Class I and II restorations* – Small direct restorations in permanent teeth (not occlusion-bearing)* – Restorations of deciduous teeth	☒	☐

<table>
<tr><td></td><td>- 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</td><td>– Liner under direct restorations of all cavity classes
– Class V restorations
– Extended fissure sealings
– Repair of composite / ceramic restorations
– Sealing of implant screw channels
*In case of occlusion-bearing restorations, apply a final layer using a sculptable composite material.</td><td></td><td></td></tr>
<tr><td>Precaution Measures/ Contraindications / Processing restrictions/ Side effects</td><td>Contraindications
- If a dry working field cannot be established, or the stipulated working technique cannot be applied
- If a patient is known to be allergic to any of the ingredients of Tetric PowerFill</td><td>Contraindications:
The use of this product is contraindicated if the patient
is known to be allergic to any of its ingredients</td><td>☒</td><td>☐</td></tr>
<tr><td>Summary of Indications, Precaution Measures/ Contraindications / Processing restrictions/ Side effects</td><td colspan="4">Tetric PowerFill and the new device Tetric plus Flow are both dental filling materials used by the dentist for the direct filling therapy in dentistry. The new device Tetric plus Flow can also be used for restoration in anterior teeth compared to the predicate.

The indications of the new device Tetric plus Flow cover the indications of Tetric PowerFill. In addition, Tetric plus Flow can be used for extended fissure sealings, repair of composite/ceramic restorations and the closure of implant screw channels..

The contraindications are basically the same for both devices. The information regarding the dry working field can be found in section “Limitations of use” for the new device.</td></tr>
<tr><td>Working Principle</td><td>Tetric PowerFill is a dental composite material for the use of direct filling in teeth.</td><td>Tetric plus Flow is a dental composite material for the use of direct filling in teeth.</td><td>☐</td><td>☒</td></tr>
<tr><td>Summary of Working Principle</td><td colspan="4">No difference</td></tr>
<tr><td>Delivery forms/dosage</td><td>Tetric PowerFill is available as syringes and cavifills in 3 different shades (IVA, IVB, IVW)</td><td>Tetric plus Flow is available as syringes and cavifils in 4 different shades (A2 plus, A3 plus, A3.5 plus, Bleach plus)</td><td>☒</td><td>☐</td></tr>
<tr><td>Summary of Delivery forms/dosage</td><td colspan="4">Tetric plus Flow is available in 4 different shades with which all classical vita shades can be covered (see table below). This innovation can be achieved due to Tetric plus Flow`s advanced chameleon effect. This chameleon effect is enabled due to an adapted recipe (see section chemical composition) compared to the predicate device.

<table><tr><th colspan="5">Shade correspondence</th></tr><tr><td>Tetric® plus</td><td>A2 plus</td><td>A3 plus</td><td>A3.5 plus</td><td>Bleach plus</td></tr><tr><td>VITA* classical shades</td><td>A1, A2, B2, C1, D2</td><td>A3, C2, C3, D3, D4</td><td>A3.5, A4, B3, B4, C4</td><td>B1, Bleach</td></tr></table>* No registered trademark of Ivoclar.</td></tr>
<tr><td>Storage Conditions</td><td>48 months at 2-28 °C / 36-82 °F</td><td>48 months at 2-28 °C / 36-82 °F</td><td>☐</td><td>☒</td></tr>
<tr><td>Summary of Storage Conditions</td><td colspan="4">No difference.</td></tr>
<tr><td>Principles of Operation</td><td>Step-by-step:
- Shade selection
- Isolation
- Cavity preparation
- Pulp protection/Base (3sCure mode is mentioned)
- Apply matrix/interdental wedge
- Conditioning/Application of the bonding agent
- Application of Tetric PowerFill</td><td>Step-by-step:
- Determining the tooth shade
- Preparing the cavity to the principles of the adhesive technique
- Ensuring isolation
- Placing the matrix
- Lining the cavity close to the pulp
- Conditioning the cavity
- Applying the composite
- Finishing/Occlusion control/Polishing</td><td>☐</td><td>☒</td></tr>
</table>

	- Finishing/Checking the occlusion/ Finishing			
TSummary Principles of operation	No difference – The principle of operation is the same for both devices.			
Summary of Chemical Composition	The main ingredients used for the predicate device Tetric PowerFill have also been used for the new device Tetric plus Flow. To achieve the advantage of the chameleon-effect, new ingredients have been used in the recipe of Tetric plus Flow. The biocompatibility has been thoroughly assessed for the new device Tetric plus Flow. This is shown in the Biological Evaluation Report for Tetric plus Flow (OTCS-Doc-ID 36395242).			
Finished Device Specification	Applicable Standards: *ISO 4049:2019 – Dentistry – Polymer-based restorative materials*	Applicable Standards: *ISO 4049:2019 – Dentistry – Polymer-based restorative materials*	☐	☒
	Applicable FDA Guidance: *Dental Composite Resin Devices – Premarket Notification [510(k) Submission]*	*Applicable FDA Guidance:* *Dental Composite Resin Devices – Premarket Notification [510(k) Submission]*	☐	☒
Summary of Finished Device Specification	Both products fulfill the requirements of ISO 4049:2019 and the FDA Guidance “Composite Resin Devices”. Values for the new device are shown in the documents “Design Verification Matrix” (see OTCS-Doc-ID 247714197 and LL252535447). The requirement depth of cure out of ISO 4049:2019 is ≥ 1.5 mm. Therefore, the Vickers hardness out of ISO 10477:2020 is considered to be the appropriate testing method to confirm higher claimed values. The differences in the claimed values sensitivity to ambient light are not considered to be significantly different, as the requirements out of the relevant ISO are met.			
Sterilization	Not applicable. No sterilization recommendation.	Not applicable. No sterilization recommendation.	☐	☒
Single use	Consumable material	Consumable material	☐	☒
Summary of Performance Specification	The device performance is tested according to ISO 4049 and the FDA Guidance “Dental Composite Resin Devices” and is substantially equivalent for the new device compared to its predicate.			

Substantial Equivalence to the predicate:

The indications of the new device **Tetric plus Fill** cover the indications of Tetric PowerFill, deviations have been explained. The working principle is basically the same for both devices. The majority of the ingredients are the same as used in the recipe of the predicate. The biocompatibility of the new formulation was fully assessed and is equivalent to Tetric PowerFill. The device performance is tested according to ISO 4049 and the FDA Guidance “Dental Composite Resin Devices” and is substantially equivalent for the new device compared to its predicate.

Therefore, **Tetric plus Fill** is substantially equivalent to the predicate device.

The indications of the new device **Tetric plus Flow** cover the indications of Tetric PowerFill, deviations have been explained. The working principle is the same for both devices. The majority of the ingredients are the same as used in the recipe of the predicate. The biocompatibility of the new formulation was fully assessed and is equivalent to Tetric PowerFill. The device performance is tested according to ISO 4049 and the FDA Guidance “Dental Composite Resin Devices” and is substantially equivalent for the new device compared to its predicate.

Therefore, **Tetric plus Flow** is substantially equivalent to the predicate device.

Differences:

Tetric plus Fill

Indication differs in that Tetric plus Fill can be used for direct veneers, for the repair of composite/ceramic restorations and the closure of implant screw channels. The application of the 3sCure mode of Bluephase PowerCure is described in the instructions for use for the new device under section “Applying the composite resin”.

Contraindications differ in that the information regarding the dry working field can be found in section “Limitations of use” for the new device.

Delivery forms/dosage differ in the number of shades and shade names. Tetric plus Fill is available in 4 different shades, which cover all classical vita shades as a result of the adapted recipe compared to the predicate.

The Chemical Composition in Tetric plus Fill uses the same main ingredients as the predicate, but new ingredients have been used in the recipe of Tetric plus Fill. The biocompatibility has been thoroughly assessed for the new device Tetric plus Fill.

There are several performance requirements that differ in the device specification- Sensitivity to ambient light, Depth of cure, Depth of cure by Vickers Hardness, and Radiopacity. The requirement depth of cure per ISO 4049:2019 is ≥ 1.5 mm. Therefore, the Vickers hardness out of ISO 10477:2020 is considered to be the appropriate testing method to confirm higher claimed values.

The differences in sensitivity to ambient light and radiopacity are not considered to be significantly different, as the relevant ISO requirements are met.

Tetric plus Flow

Indication differs in that Tetric plus Flow can be used for extended fissure sealings, repair of composite/ceramic restorations and the closure of implant screw channels.

Contraindications differ in that the information regarding the dry working field can be found in section “Limitations of use” for the new device.

Delivery forms/dosage differ in the number of shades and shade names. Tetric plus Flow is available in 4 different shades, which cover all classical vita shades as a result of the adapted recipe compared to the predicate.

The Chemical Composition in Tetric plus Flow uses the same main ingredients as the predicate, but new ingredients have been used in the recipe of Tetric plus Flow. The biocompatibility has been thoroughly assessed for the new device Tetric plus Flow.

There are several performance requirements that differ in the device specification- Sensitivity to ambient light, Depth of cure, and Depth of cure by Vickers Hardness. The requirement depth of cure per ISO 4049:2019 is ≥ 1.5 mm. Therefore, the Vickers hardness out of ISO 10477:2020 is considered to be the appropriate testing method to confirm higher claimed values.

Non-clinical performance testing:

Bench testing was performed to test the physical properties included in the Finished Device Specification for the subject device including: Sensitivity to ambient light, Depth of cure, Depth of cure by Vickers Hardness, Flexural strength, Water sorption, Solubility, Radiopacity, and Wavelength for Polymerization according to EN ISO 4049:2019 Dentistry- Polymer-based restorative materials and the FDA Guidance “Composite Resin Devices”.

Biocompatibility:

The subject devices were evaluated for Biocompatibility according to ISO 10993, ISO 7405, ISO 21726:2019 and ISO 14971:2019. The biological evaluation was performed based on toxicological data on relevant component materials / compounds, information on prior use of relevant component materials / compounds, data from biological tests, data on the history of clinical use or human exposure. Based on the information included in the biological evaluation reports it can be concluded that the products under evaluation are acceptable in relation to its clinical benefit.

The product under assessment **Tetric plus Fill** has no significant cytotoxic potential, holds no potential for material-mediated pyrogenicity, presents no risks for acute, sub-acute, sub-chronic or chronic toxicity, is not an inducer of adverse implantation effects, is not genotoxic, is not carcinogenic, and is not causing reproductive and development toxicity.

The product under assessment **Tetric plus Flow** is not cytotoxic, holds no potential for material-mediated pyrogenicity, presents no risks for acute, sub-acute, sub-chronic toxicity, is not an inducer of adverse implantation effects, is not genotoxic, not carcinogenic, and is not causing reproductive and developmental toxicity.

While Tetric plus Fill and Tetric plus Flow can cause irritation and sensitization mostly likely in its unpolymerized state. If proper safety measures (according to the IFU) during handling and use are employed, health risks can be avoided.

The products do not represent a toxicological risk for the patient and the user.

On the basis of the toxicological evaluation of the products and the longstanding worldwide clinical use of similar materials it can be concluded that the benefits provided by the final product will exceed any potential risks produced by device materials providing that the instructions for use have been followed.

Conclusion:

Tetric PowerFill and the new device **Tetric plus Fill** are both dental filling materials used by the dentist for the direct filling therapy in teeth. The advantage of using the new device Tetric plus Fill lies in the color-feature of the new device: Tetric plus Fill is available in 4 shades. However, all classical vita shades can be covered due to its chameleon effect. This effect is achieved due to an adaptation of the recipe compared to the predicate device. The physical properties of the new device are according to ISO 4049:2019 and the FDA Guidance “Dental Composite Resin”
and can be considered as substantially equivalent to Tetric PowerFill.

Therefore, **Tetric plus Fill** is substantially equivalent to the predicate device, Tetric PowerFill.

Tetric PowerFill and the new device **Tetric plus Flow** are both dental filling materials used by the dentist for the direct filling therapy in teeth. The advantage of using the new device Tetric plus Fill lies in the color-feature of the new device: Tetric plus Flow is available in 4 shades, however, all classical vita shades can be covered due to its chameleon effect. These two effects are achieved due to an adaptation of the recipe compared to the predicate device.
The physical properties of the new device are according to ISO 4049:2019 and the FDA Guidance “Dental Composite Resin” and can be considered as substantially equivalent to Tetric PowerFill.

Therefore, **Tetric plus Flow** is substantially equivalent to the predicate device, Tetric PowerFill.