December 22, 2020

Dentscare LTDA
% Rodrigo Abreu
Regulatory Specialist
United Regulatory LLC
12343 NW 25th St
Coral Springs, Florida 33065

Re: K201707
Trade/Device Name: Opallis, Opallis Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 16, 2020
Received: June 22, 2020

Dear Rodrigo Abreu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Michael Adjodha
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K201707

Device Name
Opallis and Opallis Flow

Indications for Use *(Describe)*
Opallis (Sculptable version)
The composite is suitable for use in permanent and deciduous teeth:
- Direct restorations in anterior and posterior teeth Classes I, II, III, IV, V and VI.
- Direct veneers with composites.
- Cementation of tooth fragments.
- Core build-ups.
- Teeth splinting.
- Diastema closing or reduction.
- Modification of teeth´s shape (e.g.: conoid teeth).
- Porcelain/composite repairs.

Opallis Flow (Flowable version)
- Base/lining underneath direct restorations.
- Small, non-occlusal stress-bearing class I restorations according to minimally invasive filling therapy
- Pit and fissure sealant.
- Tunnel-type preparation.
- Repair of enamel defects.
- Bonding of tooth fragments.
- Repairs in composite resin.
- Non-carious cervical lesions.
- Planning of preparation walls.

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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DENTSCARE LTDA
AV. EDGAR NELSON MEISTER, 474, JOINVILLE, SANTA CATARINA 89219-501 BRAZIL
Ph: 55 - 47 – 3441-6131

# 510(k) SUMMARY

December 10, 2020

**A) Submitter's Name:** DENTSCARE LTDA

**Owner / Operator Registration Number:** 3007210751

**Manufacture Registration Number:** 3007210751

**B) Address:** AV. EDGAR NELSON MEISTER, 474, JOINVILLE, SANTA CATARINA 89219-501 BRAZIL

**C) Phone and Fax Numbers**

**Phone:** +55 (47) 34416131

**D) Contact Person:**

Roberta Uyara

Tel.: +55 (47) 34416131

**E) Latest Revision Date:** December 10, 2020

**F) Classification Name:** Tooth shade resin material.

**Common / Usual Name:** Tooth shade resin material.

**Proprietary Name:** Opallis and Opallis Flow

**Product Code:** EBF

**Class:** Class II

**Regulation:** 21 CFR 872.3690

**G) Device Description**

**Opallis**

Opallis is a, radiopaque, light-curing composite resin with fluorescent and opalescent properties.

It is an aesthetic restorative material used for restorations of anterior and posterior teeth.

**Opallis Flow**

Opallis Flow is a light-curing composite resin used for the restoration of slightly invasive preparations, pit and fissure sealant, base/lining underneath direct restorations, in tunnel-type preparations, radiopaque lining of cavities, repairs of enamel defects, restorations of primary teeth, repairs in composite resin, bonding of tooth fragments, class I, III and V restorations, non-carious cervical lesions. Opallis Flow can be used separately or with Opallis composites.

**H) Substantial Equivalence:**

The Opallis and Opallis Flow are equivalent with the following products:

| Equivalence | 510(k) Number | Model | Company |
|---|---|---|---|
| Primary Predicate | K042819 | TETRIC EVOCERAM | IVOCLAR VIVADENT AG |
| Secondary Predicate | K993783 | TETRIC EVOFLOW | IVOCLAR VIVADENT AG |

| | | | |
|---|---|---|---|
| Reference Predicate | K191306 | Llis, Vittra APS | DENTSCARE LTDA |
| Reference Predicate | K192682 | Orthocem, Ortho Bite | DENTSCARE LTDA |

The primary and secondary predicates support substantial equivalence to the subject device, for technological characteristics, indications for use, and performance.

The reference devices support substantial equivalence for the composition comparison in the biocompatibility assessment.

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**I) Indications for Use:**

| Indications for Use Comparison | | |
|---|---|---|
| **Opallis and Opallis Flow** | **Tetric Evoceram (K042819)** | **Tetric Evoflow (K993783)** |
| **Opallis**<br>The composite is suitable for use in permanent and deciduous teeth:<br>- Direct restorations in anterior and posterior teeth Classes I, II, III, IV, V and VI.<br>- Direct veneers with composites.<br>- Cementation of tooth fragments.<br>- Core build-ups.<br>- Teeth splinting.<br>- Diastema closing or reduction.<br>- Modification of teeth´s shape (e.g.: conoid teeth).<br>- Porcelain/composite repairs.<br><br>**Opallis Flow**<br>- Base/lining underneath direct restorations.<br>- Small, non-occlusal stress-bearing class I restorations according to minimally invasive filling therapy<br>- Pit and fissure sealant.<br>- Tunnel-type preparation.<br>- Repair of enamel defects.<br>- Bonding of tooth fragments.<br>- Repairs in composite resin.<br>- Non-carious cervical lesions.<br>- Planning of preparation walls. | - Anterior restorations (Class III, IV)<br>- Class V restorations (cervical caries, root erosion, wedge-shaped defects)<br>- Restorations in the posterior region (Class I and II)<br>- Veneering of discolored anterior teeth<br>- Splinting of mobile teeth<br>- Repair of composite and ceramic veneers | - Class V restorations (cervical caries, root erosion, wedge-shaped defects)<br>- Anterior restorations (Classes III, IV)<br>- Small posterior restorations<br>- Restorative therapy for mini-cavities of all types<br>- Adhesive cementation of Sonic-Sys Inlays<br>- Extended fissures sealings in molars and pre-molars<br>- Repair of composite/ceramic veneers<br>- Blocking out of undercuts<br>- Adhesive cementation of ceramic and composite restorations |

**Discussion:**

**Opallis X Tetric Evoceram**

Opallis and Tetric Evoceram are composite resins indicated for direct restorative procedures on deciduous and permanent teeth. The range of clinical situations in which direct composites can be indicated is very wide. In addition to traditional indications for restoring cavities, direct veneers with composites, cementation of tooth fragments, core build-ups, diastema closing or reduction, modification of teeth´s shape (e.g.: conoid teeth), repair of small defects of the enamel, repair of porcelain or composite and build-ups for transparent, removable Invisalign® orthodontic retainers are examples of direct restoration (according to the Indications for use available in the manufacturer's website). As well as the use of dental splinting technique in cases of trauma and periodontal diseases. As a conclusion, the subject and the predicate have the same indication for use.

**Opallis Flow X  Tetric Evoflow**

Low viscosity light cured materials such as Opallis Flow and Tetric Evoflow are suitable for various indications such as: Base /lining, restorations made under other restorative material likewise an initial layer in all type of cavity. This main indication has as examples: Tunnel-type, planning of preparation walls.
Small restorations of all types and Small, non-occlusal stress-bearing class I restorations according to minimally invasive filling therapy: restorations made in regions that do not receive direct masticatory load.  These following indications are related to this definition: Pit and fissure sealant, Repair of enamel defects, Bonding of tooth fragments, Repair in composite resin, Non-carious cervical lesions, Class V restorations (cervical caries, root erosion, wedge-shaped defects), blocking out of undercuts.
Even though there are minor differences between the indications for use of products Opallis Flow and Tetric Evoflow (since the Tetric Evoflow, according to the Indications for use available in the manufacturer's website, is indicated for Splinting of mobile teeth and adhesive cementation of light-transmissive indirect composite and ceramic restorations) it can be concluded that both product have the same applicability.

Opallis is a condensable composite resin and Opallis Flow is its fluid counterpart for anterior and posterior restoration, such as Tetric Evoceram and Tetric Evoflow.

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## J) Technological Characteristics Comparison:

The predicate and reference devices used to establish substantial equivalence for the Opallis, and Opallis Flow devices are outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the Opallis and Opallis Flow to each of the predicate devices stratified by functional modality.

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| Device Manufacturer and Common Name | OPALLIS, OPALLIS FLOW DENTSCARE | TETRIC EVOCERAM IVOCLAR VIVADENT AG (Predicate) | TETRIC EVOFLOW IVOCLAR VIVADENT AG (Reference) |
|---|---|---|---|
| **510k #** | Not assigned yet | K042819 | K993783 |
| **Classification** | Class II | Class II | Class II |
| **Regulation #** | 21 CFR 872.3690 | 21 CFR 872.3690 | 21 CFR 872.3690 |
| **Product Code** | EBF | EBF | EBF |
| **Classification Name** | Tooth shade resin material. | Tooth shade resin material. | Tooth shade resin material. |
| **Patient Population** | All the groups | All the groups | All the groups |
| **Prescription Use** | RX only | RX only | RX only |
| **Environment** | Dental prosthetics and authorized laboratories and clinics. Opallis/Opallis Flow must be stored in temperatures between 5 - 30°C. | Dental prosthetics and authorized laboratories and clinics. Tetric EvoCeram must be stored in temperatures between 2–28°C. | Dental prosthetics and authorized laboratories and clinics. Tetric EvoFlow must be stored in temperatures between 2–28°C. |
| **Applicable Standards** | ISO 4049 ; ISO 10993 | ISO 4049; ISO 10993 | ISO 4049; ISO 10993 |
| **Device Sterilization** | Not Applicable | Not Applicable | Not Applicable |
| **Primary Package Container:** | Syringe and capsule | Syringe and capsule (cavifil) | Syringe and capsule (cavifil) |
| **Shelf life** | 3 years | Information not disclosed by the manufacturer. | Information not disclosed by the manufacturer. |
| **Use the same materials or substances in contact with the same human tissues or body fluids?** | YES | YES | YES |
| **Is the product in compliance to EN ISO 10993?** | YES | YES | YES |
| **Tissues** | Enamel and Dentin | Enamel and Dentin | Enamel and Dentin |

| | | | |
|---|---|---|---|
| **Reusable** | NO | NO | NO |
| **Duration** | Permanent | Permanent | Permanent |
| **Part of body** | Oral, teeth | Oral, teeth | Oral, teeth |
| **Is it used for the same clinical condition?** | yes | yes | yes |
| **Is it used at the same site in the body?** | yes | yes | yes |
| **Is it used in a similar population?** | yes | yes | yes |
| **Is it used for the same intended purpose?** | yes | yes | yes |
| **Is not foreseen to deliver significantly different performances?** | no | no | no |
| **Is it similar conditions of use?** | yes | yes | yes |
| **Is it similar specifications and properties** | yes | yes | yes |
| **Is it similar principles of operation?** | yes | yes | yes |

| **CLINICAL STEP** | **Opallis, Opallis Flow DentsCare** | **Tetric Evoceram Ivoclar Vivadent AG** | **Tetric Evoflow Ivoclar Vivadent AG** |
|---|---|---|---|
| **Two options: total dam isolation or relative isolation** | YES | YES | YES |
| **Application according to adhesive technique** | YES | YES | YES |
| **Size for increments** | 1,5-2mm | 1,5-2mm | 1,5-2mm |
| **Light curing unit** | POWER ≥ 450mW/cm2 and WAVELENGTH OF 400-500nm | POWER ≥ 500mW/cm2 and WAVELENGTH OF 400-500nm | POWER ≥ 500mW/cm2 and WAVELENGTH OF 400-500nm |
| **Require finishing and polishing** | YES | YES | YES |

| **Specification** | **Opallis DentsCare** | **Opallis Flow DentsCare** | **Tetric Evoceram[1] Ivoclar** | **Tetric Evoflow[1] Ivoclar** |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| **Flexural strength** | 93.38 MPa | 137.80 MPa | 120 MPa | 114 MPa |
| **Depth of cure** | Opaque shades: 2.99 mm<br>Non-opaque shades: 2.84 mm | Opaque shades: 2.97 mm<br>Non-opaque shades: 3.01 mm | > 1.5 mm | > 2.0 mm |
| **Color stability** | The observers did not attest any difference of color | The observers did not attest any difference of color | Not disclosed by the manufacturer | Not disclosed by the manufacturer |
| **Sensitivity to ambient light** | Physically homogeneous | Physically homogeneous | Not disclosed by the manufacturer | Not disclosed by the manufacturer |
| **Water sorption** | 28.93 µg/mm³ | 27.92 µg/mm³ | 21.2 µg/mm³ | 21.0 µg/mm³ |
| **Solubility** | 5.53 µg/mm³ | 5.46 µg/mm³ | < 1.0 µg/mm³ | 0.1 µg/mm³ |
| **Radiopacity** | 2.46 mm | 2.49 mm | Not disclosed by the manufacturer | Not disclosed by the manufacturer |

[1]According to Scientific Documentation disclosed by the manufacturer on https://www.ivoclarvivadent.com/zoolu-website/media/document/928/Tetric+EvoCeram+-+Tetric+EvoFlow

**Discussion:**
The subject devices are similar to the predicate devices in that they are all light-curing, radiopaque composites for restorations. The subject device, Opallis and the predicate device, Tetric EvoCeram are sculptable composites and both offer the flowable version, Opallis Flow and Tetric EvoFlow, respectively. Flowable composites are indicated for initial layer in large Class I and II, since they are more well adaptable to the cavities.
The subject devices and the predicate devices are substantially equivalent when comparing indications for use, shelf life, physical and technological properties. Considering physical properties and performance of the products, since all products meet the International Standard ISO 4049 requirements, they are substantial equivalent.

**K) Applicable Standards:**

In order to reach substantially equivalent to the predicate device the subject device Opallis and Opallis Flow were developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

**ISO 4049** - Dentistry - Polymer-based restorative materials

**ISO 10993-1** - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ENISO 10993-1:2009)

This 510(k) submission addresses the recommendation described on the Guidance for Industry and FDA Staff - Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions

**Conclusion:**

Based on compliance with the international standard and regulation mentioned above, the device Opallis and Opallis Flow demonstrate equivalency to the predicate device.

**L) Risk Management:**

In order to identified and mitigate the risks to health associated with the use of dental composite resin we have developed the risk analysis management file which includes the risk analysis method and results.

**M) Non-clinical Testing:**

In order to study the performance of the product, pre-clinical tests were performed according to the summary table below.

**Opallis**

| Test | Specification | Results |
|---|---|---|
| Sensitivity to environment lighting – ISO 4049 | According to the ISO 4049 standard, acceptance is related to the physical homogeneity of the sample, so the material was compared after the test to the same material pressed between coverslips, but without exposure to ambient light. Thus, there is no difference between the samples. | All results are within the range specified by ISO 4049. |
| Depth of Cure - | According to ISO 4049, the | All results are greater than the |

| | | |
|---|---|---|
| ISO 4049 | specification for this material is that its curing depth is: > 1.0 mm for opaque materials and > 1.5 mm for non-opaque materials. | specified threshold, therefore the material is considered to be in conformity. |
| Color tone stability after radiation and water absorption - ISO 4049 and ISO 7491 | The acceptance must be performed provided that there is no more than a small change in color, it must be proven as follows:<br><br>a) comparisons should be made by visual inspection and analyzed by three observers with normal vision, who do not identify any differences in color, this comparison must be carried at a distance of 200 to 300 mm for a period of no more than 2 seconds;<br><br>b) perform the comparison cited in a) in a light chamber at Day Light - D65 mode.<br><br>c) perform the comparison in paragraph a), by placing the specimen on a diffuse white background of 90% approximate reflectance, and it should have as a limiting size the size of the specimen, which must be surrounded by a grey background with a diffuse reflectance of 30 ± 5%. | All comparisons were carried out by three observers with normal eyesight, certified by a competent physician. They did not attest to any color difference in the samples analyzed.<br><br>The results demonstrate that the product meets ISO 4049. |
| Radiopacity - ISO 4049 | Compare the individual optical drives of each aluminum scale against the density of each scale (this check must be performed using ISO 4049 as reference). Get the value of the optical density/grey value for the δs thickness of the specimen and determine the corresponding value of aluminum, δa. | The values found in the specimens are between the second and third scale of the aluminum part, proving that the material is radiolucent according to the requirements of ISO 4049 |
| Flexing Resistance - ISO 4049 | According to the EN ISO 4049 standard the specification for flexural strength is ≥80MPa. | All results are greater than the specified threshold, therefore the material is considered as conformant. |
| Water sorption and solubility.<br><br>- ISO 4049 | Sorption: Maximum of 40 μm/mm³.<br><br>Solubility: maximum of 7.5 μm/mm³. | The results demonstrate that the product complies the specification in the EN ISO 4049 Standard. |

| | | |
|---|---|---|
| Accelerated Stability Studies | Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage. | Considering the results observed at the end of the 274 days test period, the shelf-life of 3 years in the storage condition of 30 °C for the product can be confirmed. |
| Evaluation Report of Long-Term Stability (Shelf) | Study designed to verify the physical and chemical characteristics of the product during the expected shelf life. The results are used to confirm the expiration date and storage conditions. | Considering the results observed at the end of the 36 months of the long-term test (shelf), the shelf life of 3 years in the storage condition of 30°C for the product can be confirmed. |
| Accelerated Stability Studies - Capsule | Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage. | Considering the results observed at the end of the 274 days test period, the shelf-life of 3 years in the storage condition of 30 °C for the product can be confirmed. |

**Opallis Flow**

| Test | Specification | Results |
|---|---|---|
| Sensitivity to environment lighting – ISO 4049 | According to the ISO 4049 standard, acceptance is related to the physical homogeneity of the sample, so the material was compared after the test to the same material pressed between coverslips, but without exposure to ambient light. Thus, there is no difference between the samples. | All results are within the range specified by ISO 4049. |
| Depth of Cure - ISO 4049 | According to ISO 4049, the specification for this material is that its curing depth is: > 1.0 mm for opaque materials and > 1.5 mm for non-opaque materials. | All results are greater than the specified threshold, therefore the material is considered to be in conformity. |
| Color tone stability after radiation and water absorption - ISO 4049 and ISO 7491 | The acceptance must be performed provided that there is no more than a small change in color, it must be proven as follows:<br>a) comparisons should be made by visual inspection and analyzed by three observers with normal vision, who do not identify any differences in color, this comparison must be carried at a distance of 200 to 300 mm for a period of no more than 2 seconds;<br>b) perform the comparison cited in a) in a light chamber at Day Light - D65 mode.<br>c) perform the comparison in paragraph a), by placing the specimen on a diffuse white background of 90% approximate reflectance, and it should have as a limiting size the size of the specimen, which must be surrounded by a grey background with a diffuse reflectance of 30 ± 5%. | All comparisons were carried out by three observers with normal eyesight, certified by a competent physician. They did not attest to any color difference in the samples analyzed.<br>The results demonstrate that the product meets ISO 4049. |
| Radiopacity - ISO 4049 | Compare the individual optical drives of each aluminum scale against the density of each scale (this check must be performed using ISO 4049 as reference). Get the value of the optical | The values found in the specimens are between the second and third scale of the aluminum part, proving that the material is radiolucent according |

| | | |
|---|---|---|
| | density/grey value for the δs thickness of the specimen and determine the corresponding value of aluminum, δa. | to the requirements of ISO 4049 |
| Flexing Resistance - ISO 4049 | According to the EN ISO 4049 standard the specification for flexural strength is ≥80MPa. | All results are greater than the specified threshold, therefore the material is considered as conformant. |
| Water sorption and solubility.<br>- ISO 4049 | Sorption: Maximum of 40 μm/mm³.<br>Solubility: maximum of 7.5 μm/mm³. | The results demonstrate that the product complies the specification in the EN ISO 4049 Standard. |
| Accelerated Stability Studies | Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage. | Considering the results observed at the end of the 274 days test period, the shelf-life of 3 years in the storage condition of 30 °C for the product can be confirmed. |
| Evaluation Report of Long-Term Stability (Shelf) | Study designed to verify the physical and chemical characteristics of the product during the expected shelf life. The results are used to confirm the expiration date and storage conditions. | Considering the results observed at the end of the 36 months of the long-term test (shelf), the shelf life of 3 years in the storage condition of 30°C for the product can be confirmed. |

**Conclusion:** Based on the performance test applied to this Opallis and Opallis Flow and the predicate comparison, we conclude that the subject device is substantially equivalent with the predicate.

## N) SUMMARY BIOCOMPATIBILITY DOCUMENTATION

| Biological endpoint | Test article | Rationale for why additional information isn't needed |
|---|---|---|
| **Cytotoxicity** | Orthocem UV Trace, Opallis, Vittra APS | The citotoxicity test was performed with the pool samples Orthocem UV Trace, Opallis and Vittra APS and they showed no toxic effect on the cell line V-79, so Opallis and Opallis Flow are not considered cytotoxic. |
| **Sensitization** | Orthocem UV Trace, Opallis, Vittra APS | The sensitization test was performed with the pool samples Orthocem UV Trace, Opallis and Vittra APS. Considering the test result, Opallis and Opallis Flow can be considered as non-sensitizing. |
| **Irritation or Intracutaneous reactivity** | Orthocem UV Trace, Opallis, Vittra APS | The test for irritation was performed with the pool samples Orthocem UV Trace, Opallis and Vittra APS and no alterations were observed in the oral mucosa exposed to the pool as well as in the cheek pouches of the control |

| | | |
|---|---|---|
| | | animals, so Opallis and Opallis Flow can be considered as non-irritating oral mucosa. |
| **Acute Systemic Toxicity** | Vittra APS | According to ISO 10993-1:2018, item 6.3.2.6, acute systemic toxicity tests can be combined with subacute and subchronic toxicity and implantation test protocols. |
| **Material-Mediated Pyrogenicity** | Not applicable | According to ISO 10993-1:2018, item 6.3.2.5, material-mediated pyrogenicity is rare. It has been observed in medical devices containing biologically derived material. Taking into account the chemical and physical nature of the subject devices, the existing information based on the literature regarding the chemical ingredients in the formulation and the previous experience with products with similar formulation, the test for material-mediated pyrogenicity is not applicable. |
| **Subacute/Subchronic toxicity** | Vittra APS | According to ISO 10993-1:2018, item 6.3.2.7, subacute and subchronic systemic toxicity test protocols can be expanded to include implantation test protocols to evaluate subacute and subchronic systemic and local effects. |
| **Genotoxicity** | Orthocem UV Trace, Opallis, Vittra APS | The test for genotoxicity was performed with the pool samples Orthocem UV Trace, Opallis and Vittra APS and the products did not induce gene mutations. Considering the test result, Opallis and Opallis Flow are not genotoxicity. |
| | Orthocem UV Trace, Opallis, Vittra APS | The study for genotoxicity was performed with the pool samples Orthocem UV Trace, Opallis and Vittra APS and it did not show a genotoxic effect. Considering the test result, Opallis and Opallis Flow are not genotoxicity. |
| **Implantation** | Vittra APS | The test for implantation was performed with the product Vittra APS, that is a Dentscare product previously reviewed by FDA, with more complex formulation when compared to Opallis and Opallis Flow. According to the comparative table in item 5.1, all the ingredients present in the subject devices were tested, except Bis-GMA, Bis-EMA, DDDMA and C431810 Ultra Blue, however, these ingredients are widely used in the industry and they are in the formulation of devices previously reviewed by FDA. Considering these points and the test result, Opallis and Opallis Flow can be considered non-toxic and non-irritant. |
| **Chronic Toxicity** | Not applicable | Taking into account the long term (10 years) the subject devices are in the market with no chronic toxicity reported, the test is not needed to ensure the safety. |
| **Carcinogenicity** | Not applicable | Considering literature reviews and wide knowledge regarding the chemical ingredients in the formulation and |

| | | |
|---|---|---|
| | | the previous experience with products with similar formulation, the products are not carcinogenicity potential, so the test for carcinogenicity is not applicable. |

**CONCLUSION**

In accordance to results of biocompatibility tests ISO 10993 carried out with Opallis, taking into account the results of test with Vittra APS (more complex chemical composition) and given the time the Opallis family of products has been on the market, we can assure that the Opallis and Opallis Flow are biocompatible for using in human patients.