July 1, 2022

Ultradent Products, Inc.
% Dave Yungvirt
Most Responsible Person
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K221909
Trade/Device Name: J-Temp
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: June 27, 2022
Received: June 30, 2022

Dear Dave Yungvirt:

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,

Michael E. Adjodha, M.ChE.
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)*

K221909

Device Name
J-Temp

Indications for Use *(Describe)*

•Temporary restorations
•Splinting between implant copings for impressions to resist impression material distortion
•To provide structure for isolation clamping and to act as a barrier for endodontic irrigants
•Bite ramps and temporary occlusal buildups during orthodontics

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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South Jordan, UT 84095
Est. Reg. No. 1718912

K221909

510(k) Summary

This summary of the traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 J-Temp.

I. Applicant's Name and Address

Ultradent Product, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Contact Person:	Mr. Matthew Buck
Title:	Regulatory Affairs Specialist III
Telephone:	801-553-4339
Cell Phone:	801-201-2371
Fax:	801-553-4609

Date Summary Prepared: 20 May 2022

II. Name of the Device

Device:	Material, Tooth Shade, Resin
Trade/Device Name:	J-Temp
Common Name:	Material, Tooth Shade, Resin
Review Panel:	Dental
Regulation Number:	21 CFR 872.3690
Device Class:	Class II
Classification Product Code:	EBF

III. Device Description

J-Temp temporary resin is a flowable resin material designed to be durable enough to stay in place after being applied. It is delivered via syringe and light cured.

IV. Statement of Intended Use

J-Temp is indicated for

- Temporary restorations
- Splinting between implant copings for impressions to resist impression material distortion.

- To provide structure for isolation clamping and to act as a barrier for endodontic irrigants
- Bite ramps and temporary occlusal buildups during orthodontics

V. Predicate Device

J-Temp identified primary predicate: Clip Flow by Voco (K153493)

VII. Comparison of Technological Characteristics

Predicate technological comparison:

The technology, delivery, and intended use of J-Temp are substantially equivalent to the identified predicate as outlined in Table 5-1:

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Table 5-1: UltraTemp REZ II substantial equivalence comparison

Descriptive Information/ characteristic	Predicate: Clip Flow (K153493)	Device: J-Temp	Reference: Venus Flow (K033665)	Reference: TKO Composite Bite Turbo Gel (K210349)	Identified Characteristic Differences and Rationale for Differences
Product Code	EBF	EBF	EBF	EBF	Same
Intended Use	[A] Temporary inlay and onlay treatments of the cavity [B] Sealing of openings for implant screws [C] Relining material for temporary crowns and bridges [D] Block-out material for retentive areas in the dental arch, e.g. before taking impressions [E] Covering of the gingival margin [F] Fixing of resin matrix during filling placement [G] Temporary filling of cavities	•Temporary restorations •Splinting between implant copings for impressions to resist impression material distortion •To provide structure for isolation clamping and to act as a barrier for endodontic irrigants •Bite ramps and temporary occlusal buildups during orthodontics	Venus flow is a flowable, light curing, radiopaque hyrbrid composite used for adhesive, tooth-colored anterior and posterior restorations. Due to its low viscosity Venus Flow provides excellent coverage tooth structure. Applicable applications includes: Baseliner in Class I & II cavities; Fissure sealing; Enlarged fissure sealing; Class V fillings; Minimally invasive Class I and II fillings in areas not subjected to masticatory forces; Minimally invasive Class III fillings; Smaller contour and shade adjustment on the enamel and dentine; Small surface repairs to direct and indirect restorative in	TKO is a pink, flowable light cure composite gel for the creation of occlusal buildups (bite turbos) and as a retainer repair composite.	Both Clip Flow and J-Temp have the same intended use with minor differences in their Indications for use. Clip Flow is indicated for temporary inlay and onlay treatments of the cavity, temporary filling of cavities. J-Temp is indicated for temporary restorations. J-Temp is indicated for providing structure for isolation clamping acting as a barrier for endodontic irrigants, because when cured it is harder than Clip Flow it can be used in this specific procedure as part of a temporary filling. Because J-Temp is harder when cured it can be indicated for splinting between implant copings for impressions to resist impression material distortion, like the reference device Venus Flow which has an indication to splint teeth. J-Temp can also be indicated for Bite ramps and temporary occlusal buildups during orthodontics like

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			combination with a suitable bonding agent**; Splinting teeth;** Cavity lining; Bracket retention; Sealing endodontically treated teeth; Luting porcelain or composite veneers; Filling in voids in temporary crown and bridges materials		the reference device TKO Composite Bite Turbo Gel.
Intended User	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Dental Professional	Same intended user. No identified differences.
Characteristics	• Flowable, light-cured temporary restorative material. • Elastic consistency and removable with probe.	• Flowable, light-cured temporary restorative material. • Cured resin removable with dental bur.	• Flowable, light-cured restorative material.	• Flowable, light-cured composite Gel	Clip Flow and J-Temp are flowable light-cured temporary restorative materials. They are both intended to be easily removed as temporary materials unlike the reference devices.
Composition	• Methacrylates • Light cure initiators BHT	• Methacrylates • Light cure initiators • Glass ionomer fillers Pigments	• Methacrylates • Light cure initiators • Barium Aluminum Boro Fluor Silicate fillers • Pigments • BHT	• Methacrylates • Light cure initiators Pigments	Clip Flow and TKO Composite Bite Turbo Gel don't have fillers. Rationale for differences: J-Temp and Venus Flow have indications for use that require a harder material. J-Temp doesn't need BHT which is free radical inhibitor.

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Delivery System or Deployment Methods	Product is provided in a 1.8g syringe with disposable delivery tips	Product is provided in a 1.2mL syringe with disposable delivery tips	Product is provided in a 1.8g syringe	Product is provided in a precision 3.5 gm LuerLoc syringe with tips	Clip Flow and the J-Temp are provided in similar delivery syringes along with the reference devices.
Physical Properties	• Flowable • Used with tips. • Light cured • ≤ 5 % shrinkage • ≤ 10 HK Hardness • ≥ 1 mm depth of cure	• Flowable • Used with tips. • Light cured • ≤ 5 % shrinkage • ≥ 10 HK Hardness • ≥ 1 mm depth of cure • Light sensitivity greater than 60 seconds • ≥ 2 MPa Flexural Strength • ≥ 180 MPa Compressive Strength • Remove with bur Radio-opaque	• Flowable • Used with tips. • Light cured • ≥ 1 mm depth of cure • Light sensitivity greater than 60 seconds • ≥ 2 MPa Flexural Strength • ≥ 180 MPa Compressive Strength • Remove with bur Radio-opaque	• Flowable • Used with tips. • Light cured. • ≥ 10 HK Hardness • ≥ 1 mm depth of cure • Light sensitivity greater than 60 seconds • ≥ 2 MPa Flexural Strength • ≥ 180 MPa Compressive Strength Remove with bur	J-Temp is harder when cured than Clip Flow. J-Temp has a hardness value comparable to TKO Composite Bite Turbo Gel. J-Temp's flexural strength is less than Venus Flow and to TKO Composite Bite Turbo Gel. J-Temp is radio-opaque, and Clip Flow is not radio-opaque.
Patient Population	is suitable for use in all patients without any age or gender restrictions	Individuals of all ages and gender and shall be assessed by the administering dental professional.	The dental material is suitable for patients requiring dental treatment for the indications	Individuals receiving orthodontic treatment.	N/A

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			with consideration of the contraindications.		
Biocompatibility and Safety	Biocompatible	Tested per ISO 7405, ISO 10993-1 •Physical/Chemical Information •Systemic Toxicity •Genotoxicity •Cytotoxicity •Sensitization •Irritation •Implantation Effects	Biocompatible	ISO 10993-5 ISO 7405:2018	The Clip Flow and J-Temp are shown to be biocompatible as well as the reference devices.

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VII Conclusion:

As outlined in the comparison table above, J-Temp is similar to the identified predicate device with respect to its intended use, its Intended User, the Device Design, Types of Material used, Delivery System and or Deployment Method, Physical Properties and Patient Population. Also, J-Temp does not introduce any new safety or efficacy issues, questions or concerns per Biocompatibility and Safety testing that has been completed. The subject device also successfully passed all verification and validation testing.

In summary it can be stated that the development of the subject J-Temp product is based on a well-established technology in the form of the predicate Clip Flow product. Based on these comparisons to the predicate device, we believe that J-Temp is substantially equivalent to the predicate device and do not raise new concerns of safety or efficacy.