CMP Industries LLC
Devon Howe
President & CEO
413 North Pearl Street
Albany, New York 12207

October 2, 2017

Re: K170375
Trade/Device Name: Nobilplast Denture Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: July 26, 2017
Received: July 28, 2017

Dear Devon Howe:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170375

Device Name
Nobilplast Denture Resin

Indications for Use *(Describe)*
Nobilplast Denture Resin is intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

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.

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ISO 13485:2003

K170375 Nobilplast Denture Resin 510(k) Summary
September 28, 2017

Name of Submitter: Devon O. Howe
Address: 413 N. Pearl St., Albany, NY 12207
Telephone number: 518-434-3147
Contact person: Devon O. Howe
Date the summary was prepared by the submitter: September 28, 2017
Company: CMP Industries LLC
Classification/Generic Name: denture resin
Device Name: Nobilplast Denture Resin
Product Code: EBI
Classification: II

Device Description: Nobilplast Denture Resin is a polyamide (nylon) resin available in pink and white colors. The resin granules are packaged in injectable aluminum cartridges or sold in a bulk container where users can fill empty aluminum cartridges that are sold separately.

Indications for Use:

Nobilplast Denture Resin is intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Design: Nobilplast Denture Resin is designed exactly following K072402 FlexStar V. Both products share the same material type (polyamide), pigments, shading operation, packaging configuration, packaging equipment/process and quality system.

Materials Used: Nobilplast Denture Resin is a polyamide (nylon) that is nearly identical to K072402 FlexStar V. Nobilplast Denture Resin is part of a delivery system that includes aluminum cartridges.

Performance Testing: Nobilplast Denture Resin was subjected to several bench tests to characterize its properties including: Density per ASTM D792, Melting Point per ISO 11357, Hardness Shore per ISO 868, Tensile per ISO 527, Ultimate Flexural and

Flexural Modulus per ISO 178, Charpy Impact ISO 179/1eU, Sorption & Solubility per ISO 20795, DSC Analysis per ASTM D3418, TGA Analysis per ASTM E1311, Melt Flow Rate Analysis, Izod Impact Strength per ISO 180 or ASTM D256.

Primary Predicate Device: K072402 FlexStar V Resin

Reference Devices: K130680 High Denture Resin, (pre-amendment) Valplast, K053060 TCS Unbreakable

Biocompatibility: Nobilplast Denture Resin was used to make partial dentures in final finished form as test articles that were used in biological testing as suggested by FDA Guidance: Cytotoxicity, Irritation and Sensitization. The testing results indicate no biocompatibility issues exist for Nobilplast Denture Resin.

Shelf Life: Nobilplast Denture Resin has a 5-year shelf-life demonstrated by real-time packaging study on the nearly identical product: FlexStar V. Details are in Section 11, Attachment 1.

Substantial Equivalence: The polyamide resin of FLEXSTAR V, Dentsoll Rezen NF, TCS Unbreakable and Valplast are very similar in formulations, presentation and colors to Nobilplast Denture Resin. The polymer used for FLEXSTAR V (primary predicate) is the same brand name (Rilsan) as used for Nobilplast and they both share the same pigments and packaging systems and configurations. FLEXSTAR V and Nobilplast Denture Resin have the same intended use. Dentsoll Rezen NF, TCS Unbreakable and Valplast and FlexStar have the same intended use as Nobilplast. The bench and biological tests on Nobilplast Denture Resin demonstrate that safety and effectiveness is as good as the predicate devices.

Substantial Equivalence Table

		Primary Predicate	Reference Device	Reference Device	Reference Device
Property	Nobilplast Denture Resin	FLEXSTAR V (K072402)	TCS Unbreakable (K053060)	DENTSOLL Rezen NF (K130680)	VALPLAST (9008371) Pre-amendment
Intended Use	Nobilplast Denture Resin is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. Note: The likelihood that anyone would use Nobilplast Denture Resin for *relining, repairing, and rebasing* dentures is extremely low, which is why it was omitted from the indication for use. There are many other ways to perform these procedures which are faster, easier, cheaper and more effective. Note: Occlusal splint is the same as a "bite plate" as shown in DENTSOLL. Note: "personal trays" is the same as an impression tray. No one will use this type of material for this application, which why it was omitted from Nobilplast Denture Resin.	FLEXSTAR V is used for the fabrication of partial or full removable dentures, as well as occusal splints and night guards.	TCS® Unbreakable is a break resistant material used in the fabrication and repair of base plates for removeable dental prosthetic appliances where superior flexibility and patient comfort for the lifetime of the prosthetic are significant concerns. This includes, but not to be limited to, full and partial dentures, orthodontic devices, occlusal splints, and night guards.	Intended for manufacturing, *relining, repairing, and rebasing* of partial or full removable dentures, dental plates, *bite plates*, *personal trays*, appliances, occlusal splints and night guards.	Valplast is used for the fabrication of partial or full removable dentures, Cosmetic Gum Veneers, Nightguards and Occlusal Splints, Onlays. Valplast applications can be found here: https://www.valplast.com/special-applications-1/

		Primary Predicate	Reference Device	Reference Device	Reference Device
Property	Nobilplast Denture Resin	FLEXSTAR V (K072402)	TCS Unbreakable (K053060)	DENTSOLL Rezen NF (K130680)	VALPLAST (pre-amendment)
Type and Class	Type III, Class 1	Type III, Class 1	Type III, Class 1	Type III, Class 1	Type III, Class 1
Chemical Family	Polyamide	Polyamide	Polyamide	Polyamide	Polyamide
CAS Number	CAS# 25587-80-8	CAS# 25587-80-8	unknown	25038-97-5	unknown
Material used to invest	Dental Stone	Dental Stone	Dental Stone	Dental Stone	Dental Stone
Storage Temperatur	60°F – 90°F	60°F – 90°F	Store in a dry, cool and well-ventilated place	60°F – 90°F	Store in cool dry area
Dosage	1 cartridge	1 cartridge	1 cartridge	1 cartridge	1 cartridge
Processing Time/Temperature	11 minutes @ 550°F (290°C) (furnace heats one cartridge at a time)	11 minutes @ 550°F (290°C) (furnace heats one cartridge at a time)	11 minutes @ 550°F (288°C) (furnace heats one cartridge at a time)	25 minutes @ (260°C) (furnace heats 6 cartridges at a time)	11 minutes @ 550°F (290°C) (furnace heats one cartridge at a time)
Injection Time	3 minutes (using manual press)	3 minutes (using manual press)	3 minutes (using manual press)	5 minutes (using air-powered press)	3 minutes (using manual press)
Cool Time	30 minutes	30 minutes	30 minutes	30 minutes	30 minutes
Physical Properties	Partial denture is semi-flexible: Thick sections are rigid to hold denture teeth into place while thinner areas, such as clasps, are slightly flexible to accommodate undercuts on abutment teeth.	Same as Nobilplast Denture Resin	Physical properties have not been bench tested.	Same as Nobilplast Denture Resin	Same as Nobilplast Denture Resin

Conclusion: Nobilplast Denture Resin is substantially equivalent to FLEXSTAR V and Dentsoll Rezen NF and TCS Unbreakable and Valplast. All five products have indications for use that are primarily for partial and full dentures. While Rezen NF and Valplast indicate alternative applications, in practice, they are not used for these alternative applications with any regularity. All five are made from the same type of polymer and have similar injection and cooling times. They are all Type III class I denture materials. The processing temperatures are the same between Nobilplast Denture Resin and TCS Unbreakable and FLEXSTAR V and Valplast and similar to Dentsoll Rezen NF. Nobilplast Denture Resin is substantially equivalent as demonstrated by biological testing conducted on finished form partial dentures.