



Food and Drug Administration  
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September 14, 2015

3M Deutschland GmbH  
Dr. Desi W. Soegiarto  
Group Leader Regulatory Affairs  
ESPE Platz  
Seefeld, Bavaria 82234

Re: K151144

Trade/Device Name: SuPro 100  
Regulation Number: 21 CFR 872.3770  
Regulation Name: Temporary crown and bridge resin  
Regulatory Class: II  
Product Code: EBG  
Dated: August 05, 2015  
Received: July 31, 2015

Dear Dr. Soegiarto:

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 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" (21CFR 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 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 yours,

 Tina  
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known)

K151144

Device Name

SuPro 100

Indications for Use (Describe)

- Fabrication of temporary crowns, bridges, inlays, onlays, and veneers
- Fabrication of long-lasting temporary restorations
- Lining material for prefabricated temporary crowns made of composite (e.g., Protemp™ Crown) and metal (e.g., Iso-Form crowns)

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**K151144: 510(k) SUMMARY**Submitter

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 Date: ..... April 27, 2015  
 ..... (revised on September 10, 2015)

Name of Device

Product Code: ..... EBG  
 Common Name: ..... Composite based temporary crown and  
 ..... bridge material  
 Classification: ..... Crown and Bridge, Temporary, Resin  
 Regulation Number: ..... 21 CFR 872.3770  
 Proprietary Name: ..... SuPro 100

Predicate Device

TempXN28.....K073296  
 .....by 3M Deutschland GmbH, Germany

### Description for the Premarket Notification

SuPro 100 is classified as temporary crown and bridge resin (21 C.F.R. § 872.3770, Class II device).

As its predicate device TempXN28 (K073296, by 3M Deutschland GmbH - Germany), SuPro 100 is a composite material based on multifunctional methacrylates esters, therefore, both TempXN28 and SuPro 100 as two-component system have filling material-like properties. As TempXN28, Supro 100 will be available in Garant™ mixing and dispensing system (by 3M Deutschland GmbH, Germany).

Investigations have been carried out to characterize the performance of SuPro 100 to be used for fabrication of temporary restorations.

Comparison for indications for use, performance, and chemistry shows that SuPro 100 is substantially equivalent to the predicate device.

Physical and mechanical properties have been compared to properties of TempXN28.

Comparison showed that physical and mechanical properties of SuPro 100 are substantially equivalent to TempXN28.

Biocompatibility evaluations have been performed for SuPro 100 in consideration of FDA & internationally recognized guidelines. The conclusion of the assessments is that SuPro 100 is biocompatible for its intended use.

### Indications for Use

- Fabrication of temporary crowns, bridges, inlays, onlays, and veneers
- Fabrication of long-lasting temporary restorations
- Lining material for prefabricated temporary crowns made of composite (e.g., Protemp™ Crown) and metal (e.g., Iso-Form crowns)

**Tab. Substantial equivalence: Comparisons**

<b>Indications for Use</b>	<b>SuPro 100</b>	<b>TempXN28 (K073296)</b>
	Fabrication of temporary crowns, bridges, inlays, onlays, and veneers	Fabrication of temporary crowns, bridges, inlays, onlays, and veneers
	Fabrication of long-lasting temporary restorations	Fabrication of long-lasting temporary restorations
	Lining material for prefabricated temporary crowns made of composite (e.g., Protemp™ Crown) and metal (e.g., Iso-Form crowns)	Lining material for prefabricated temporary crowns made of composite (e.g., Protemp™ Crown) and metal (e.g., Iso-Form crowns)
<b>Technological Characteristic</b>	<b>SuPro 100</b>	<b>TempXN28 (K073296)</b>
	Delivery: Garant™ mixing and dispensing system	Delivery: Garant™ mixing and dispensing system
	Composite material based on multifunctional methacrylate esters	Composite material based on multifunctional methacrylate esters
	Two component system: Base paste and catalyst paste	Two component system: Base paste and catalyst paste

### Physical and Mechanical Properties

Comparative testing was performed for both SuPro 100 and the predicate device TempXN28 (K073296) for all tests listed below

Test	Results
Flexural strength [MPa]	Flexural strength of SuPro 100 was higher than that of TempXN28.
e-Modulus [GPa]	e-Modulus of SuPro 100 was higher than that of TempXN28.
Deflection [mm]	Deflection values of SuPro 100 was comparable to that of TempXN28.
Compression strength [MPa]	SuPro 100 shows lower values for compressive strength in compare to that of TempXN28.
Compression at break [%]	SuPro100 has lower compression percentage at break compared to TempXN28.
Tensile strength [MPa]	Tensile strength of SuPro 100 was higher than that of TempXN28.
Elongation at break [%]	Value for the elongation till break of SuPro 100 was comparable to that of TempXN28.
Impact strength [kJ/mm <sup>2</sup> ]	Impact strength of SuPro 100 was comparable to that of TempXN28.
Surface hardness (Vickers scale): 1d, 36°C in water & 4d, 36°C in water	SuPro 100 had a significantly higher surface hardness compared to TempXN28.
Temperature peak (1cm <sup>3</sup> Volume) [°C]	The maximum temperatures resulting from the polymerization reaction were comparable for SuPro 100 and TempXN28.
Setting characteristics (Physica; 23°C). Working time (tA) [min], Final setting (tE) [min], Setting transition (dt) [min]	Compared to TempXN28, SuPro 100 generally has a faster setting. Working time, transition time and final setting time are shorter for SuPro 100.
ACTA abrasion (3 body wear)	SuPro 100 had a similar abrasion behavior in the ACTA 3 body wear test in compare to TempXN28.
Chewing simulation volume loss [µm <sup>3</sup> ]	SuPro 100 had lower rate of volume loss than TempXN28.
Elcometer Abrasion depths samples [µm]	Abrasion of SuPro 100 is lower than of TempXN28.
Elcometer Volume loss steatite antagonist [mm]	SuPro 100 showed lower rate of wear on the steatite antagonist in compare to TempXN28.

Following Standards have been referenced for both SuPro 100 and the predicate device TempXN28 (K073296):

There are no standards specifically for temporary crown and bridge materials. Therefore, for some material testing standards were referenced: ISO 179-1, ISO 527-1, ISO 4049, ISO 9917.

Biocompatibility: ISO 7405, ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-12

Risk Management: ISO 14971

Main difference between SuPro 100 and TempXN28 is amount of fillers. To improve mechanical properties e.g. flexural strength, e-Modulus and tensile strength, amount of fillers of SuPro 100 is increased in compare to TempXN28 (SuPro 100: approx. 50% of its weight, TempXN28: approx. 33% of its weight).

SuPro 100 and its predicate device TempXN28 (K073296) are very similar in material class, composition, and technology. SuPro 100 and TempXN28 have same indications for use and procedure as bis-acrylic composite dental temporary materials. Comparisons showed that physical and mechanical properties of SuPro 100 are comparable to those of TempXN28. Both SuPro 100 and TempXN28 are biocompatible for its intended use. In summary, it can be concluded that SuPro 100 is substantially equivalent to the predicate device TempXN28 (K073296).