



Food and Drug Administration
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Silver Spring, MD 20993-0002

October 22, 2015

Neosil Co., Ltd
c/o Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group Usa, Inc.
2651 E Chapman Ave Ste 110
Fullerton, California 92831

Re: K152180
Trade/Device Name: PEAK
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: July 29, 2015
Received: August 4, 2015

Dear Ms. Chung:

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" (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 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)
K152180

Device Name
PEAK

Indications for Use (Describe)

NS033C is to be used as a light body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Silicon dental impressions
- Crown/bridge work
- Inlays, Onlays

NS017C/NS017T is to be used as a heavy body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

MSP is to be used as a putty body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

MSBC is to be used as a bite type for:

- Making accurate occlusal registrations
- Standards bite registrations in the end bite position.
- Key material for needle point registration.
- Production of small model segments

MSRC is to be used as a regular body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Reline impressions
- Crown/bridge work
- Inlays, Onlays

MSCC is to be used as a regular body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Reline impressions
- Crown/bridge work
- Inlays, Onlays

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary (K152180)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: October 21, 2015

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	PEAK
Common Name:	Dental Impression Material
Classification Name:	Material, Impression
Classification:	Class II, 21 CFR 872.3660
Classification Product Code:	ELW

4. Predicate Device:

BONASIL A+ by DMP, Limited (K102836)

5. **Device Description:**

PEAK is a two component (base paste and catalyst, mixing ratio 1:1) vinyl polysiloxane impression material to be used for impressions, where typically alginates are used. The PEAK offers four different viscosities (light, heavy, putty and regular) in delivery systems of cartridges and jars. The device includes accessories such as a spoon.

PEAK offers one light body type: NS033C.

PEAK offers two regular body types: MSRC and MSCC with different material compositions and color. The MSCC has clear appearance.

PEAK offers two heavy body types: NS017C/NS017T and MSBC with different material compositions and color. MSBC is a bite type particularly.

6. **Intended Use:**

NS033C is to be used as a light body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Silicon dental impressions
- Crown/bridge work
- Inlays, Onlays

NS017C/NS017T is to be used as a heavy body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

MSP is to be used as a putty body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

MSBC is to be used as a bite type for:

- Making accurate occlusal registrations
- Standards bite registrations in the end bite position.
- Key material for needle point registration.
- Production of small model segments

MSRC is to be used as a regular body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Reline impressions
- Crown/bridge work

- Inlays, Onlays

MSCC is to be used as a regular body material for:

- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Reline impressions
- Crown/bridge work
- Inlays, Onlays

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- ISO 4823 - Consistency Test, Mixing Time Test, Working Time Test, Detail Reproduction Test, Test for Compatibility with Gypsum, Linear Dimensional Change Test, Elastic Recovery Test, and Strain-in-Compression Test
- ISO 10993-5 – Cytotoxicity Test
- ISO 10993-10 - Skin Sensitization Test, Oral Mucous Irritation Test
- ISO 10993-11 – Acute Systemic Toxicity Test
- Other bench testing – Shelf life, Visual Inspection, Weight and Component Color Check

8. Substantial Equivalence

The PEAK is substantially equivalent to the predicate device described herein with respect to intended use, device design, accessory components, base material and delivery method. Also the curing mechanism of the subject device and the predicate devices is substantially equivalent in principle. This supports that the compatibility of the subject device are substantially equivalent to the predicate devices.

The difference might be the compositions of some materials; however, the biocompatibility and the results of performance testing performed according to ISO 4823 show that this difference does not raise issues in safety and effectiveness.

	Subject Device	Predicate Device
510(K) Number	N / A	K102836
Trade Name	PEAK	BONASIL A+
Manufacturer	Neosil Co., Ltd	DMP, Limited
Product Code	ELW	ELW
Intended Use	NS033C is to be used as a light body material for: <ul style="list-style-type: none"> ▪ Two step putty/wash technique 	Bonasil A+ Light (light normal set, light fast set) is to be used as a light body material for : <ul style="list-style-type: none"> ▪ Two step putty/wash technique

	<ul style="list-style-type: none"> ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Silicon dental impressions ▪ Crown/bridge work ▪ Inlays, Onlays <p>NS017C/NS017T is to be used as a heavy body material for:</p> <ul style="list-style-type: none"> ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work ▪ Inlays, Onlays <p>MSP is to be used as a putty body material for:</p> <ul style="list-style-type: none"> ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work ▪ Inlays, Onlays <p>MSBC is to be used as a bite type for:</p> <ul style="list-style-type: none"> ▪ Making accurate occlusal registrations ▪ Standards bite registrations in the end bite position. ▪ Key material for needle point registration. ▪ Production of small model segments <p>MSRC is to be used as a regular body material for:</p> <ul style="list-style-type: none"> ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Reline impressions ▪ Crown/bridge work ▪ Inlays, Onlays <p>MSCC is to be used as a regular body material for:</p> <ul style="list-style-type: none"> ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Reline impressions ▪ Crown/bridge work ▪ Inlays, Onlays 	<ul style="list-style-type: none"> ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Reline impressions ▪ Crown/bridge work ▪ Inlays, Onlays <p>Bonasil A+ Heavy (heavy normal set, heavy fast set) is to be used as a heavy body material for :</p> <ul style="list-style-type: none"> ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work ▪ Inlays, Onlays <p>Bonasil A+ Putty (putty normal set, putty fast set, putty soft, putty extra hard, lab putty) is to be used as a preliminary material for :</p> <ul style="list-style-type: none"> ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work ▪ Inlays, Onlays <p>Bonasil A+ Bonabite (bonabite fast set) is to be used as a light body material for :</p> <ul style="list-style-type: none"> ▪ Making accurate occlusal registrations ▪ Standards bite registrations in the end bite position. ▪ Key material for needle point registration. ▪ Production of small model segments
Raw Material	Vinyl polysiloxane	Vinyl polysiloxane
Human Factor	Ready to use dispensing system	Ready to use dispensing system
Biocompatibility	Biocompatible conforming to ISO 10993-1	Biocompatible conforming to ISO 10993-1

Physical Properties	<p>Meets ISO 4823 specifications</p> <p>1) NS033C - Working time : more than 40sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 3</p> <p>2) NS017C/NS017T - Working time : more than 40sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 1</p> <p>3) MSP - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 0</p> <p>4) MSBC - Working time : more than 30sec - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 1</p> <p>5)MSRC - Mixing time : more than 30sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 2</p> <p>6)MSCC - Mixing time : more than 30sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 2</p>	<p>Meets ISO 4823 specifications</p> <p>1) Bonasil A+ Light - Working time : about 120sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 3</p> <p>2) Bonasil A+ Heavy - Working time : about 120sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 1</p> <p>3) Bonasil A+ Putty - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 0</p> <p>4) Bonasil A+Bonabite - Working time : about 30sec - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 2 - Hardness : more than 20HD</p>
Mixing ratio	1:1	1:1
Sterility	Non-sterile	Non-sterile

9. Conclusion:

Based on the testing results, Neosil Co., Ltd. concludes that the PEAK is substantially equivalent to the predicate devices.