Neosil Co., Ltd.
Yang Ho Dong
CEO
Onbix Corporation
#821 Samil Plaza, 14, Dogok-ro 1-gil, Gangnam-gu
Seoul, 06523 Kr

June 13, 2018

Re: K180565
Trade/Device Name: PEAK NS033CF, PEAK NS017CF
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: February 26, 2018
Received: March 19, 2018

Dear Yang Ho Dong:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K180565

Device Name
PEAK NS033CF
PEAK NS017CF

Indications for Use *(Describe)*
this device is to be used as a heavy body material for:
- Two step putty/wash technique
- Sigle step putty/wash technique
- Functional peripheries
- Crown/bridge work

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) SUMMARY
K180565

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

Submitter Information: **Neosil Co., Ltd.**
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Date Summary Prepared: Mar 23, 2018

Device Information:

Trade Name(s):	PEAK NS033CF / PEAK NS017CF
Classification Name:	impression material
Panel:	dental
Product Code & Regulation:	ELW

Predicate Device Information:
K152180 - PEAK NS033C / PEAK NS017C

Device Description:
Vinyl polysiloxane is an addition-reaction silicone elastomer (an addition silicone). It is a viscous liquid that cures quickly into a rubber-like solid, taking the shape of conforming to tooth's shape surface it was lying against while curing. As with 2-part epoxy, its package keeps its 2 component liquids in separate container until the moment they are mixed and applied, because once mixed, they cure (harden) rapidly.
To create the material, the user mixes the base with the catalyst, and the chemical reaction begins. Once the impression material is set and modified, it is taken to patient′'s mouth for use in the transfer bonding process.

Indications for Use:
this device is to be used as a heavy body material for:

- Two step putty/wash technique
- Sigle step putty/wash technique
- Functional peripheries
- Crown/bridge work

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* raw material
* technological characteristics including setting time, consistency, elastic recovery, strain-in compression etc in accordance with ISO 4823.
* performance properties
* biocompatibility in accordance with ISO 10993-1

Summary of the technological characteristics compared to the predicate device
The device chemical composition is slightly different than listed in the predicate and therefore the following performance and biocompatibility tests were carried out to show substantial equivalence.

Non-Clinical performance test
To be in compliance with electromagnetic safety and compatibility, appropriate study has been applied to the new device in accordance with the following standard

ISO 10993-5 cytotoxicity
ISO 10993-10 skin irritation, sensitization
ISO 4823:2015 dentistry – elastomeric impression materials

Conclusion
The subject and predicate devices have similar material properties , characteristics and performance and therefore is substantially equivalent to the K152180 predicate device.