Meta Biomed Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

November 15, 2018

Re: K181689
Trade/Device Name: Nexcomp
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: October 12, 2018
Received: October 17, 2018

Dear April Lee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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 -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.15 12:44:18 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181689

Device Name
Nexcomp

Indications for Use *(Describe)*
Nexcomp is intended to restore carious lesions or structural defects in teeth. It is indicated for Class I, II, III, IV, and V restorations, core-buildup to replace missing tooth structure, for splinting and for diastema closure, direct veneers, composite and porcelain repairs.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter
META BIOMED CO., LTD.
Suk Song Oh
270, Osongsaengmyeong 1-ro, Osong-eup,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,
Korea
Email: ef1459@metabiogw.bizmeka.com
Phone: +82-43-230-8841
Fax: +82-43-217-1983

Official Correspondent
Withus Group Inc
April Lee
106 Superior,
Irvine, CA 92620
USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: Nexcomp
- Classification Name: Tooth Shade Resin Material
- Product Code: EBF
- Panel: Dental
- Regulation Number: 21 CFR 872.3690
- Device Class: Class II
- Date prepared: 11/08/2018

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

- K080305, Nexcomp manufactured by Meta Biomed Co., Ltd.

General Description

Nexcomp is a light-cured, esthetic, resin-based dental restorative designed for direct placement in both anterior and posterior restorations. The material is radiopaque and indicated for all types of cavity preparations. The hybrid blend has an ultra-fine filler and 40 nm silica particles. Nexcomp will be marketed in 19 shades which corresponded with the Vita Shade Guide.

Indication for Use

Nexcomp is intended to restore carious lesions or structural defects in teeth. It is indicated for Class I, II, III, IV, and V restorations, core-buildup to replace missing tooth structure, for splinting and for diastema closure, direct veneers, composite and porcelain repairs.

Comparison of technological Characteristics with Predicate Devices:

	Specification	Subject Device	Primary Predicate Device
Manufacturer	-	META BIOMED CO., LTD.	META BIOMED CO., LTD.
Device Name	-	Nexcomp	Nexcomp
510(k) Number	-	K181689	K080305
Classification Name	-	Tooth Shade Resin Material	Tooth Shade Resin Material
Product Code	-	EBF	EBF
Regulation Number	-	21 CFR 872.3690	21 CFR 872.3690
Indications for Use	-	Nexcomp is intended to restore carious lesions or structural defects in teeth. It is indicated for Class I, II, III, IV, and V restorations, core-buildup to replace missing tooth structure, for splinting and for diastema closure, direct veneers, composite and porcelain repairs.	
Principle of operation	-	Nexcomp is visual light curing polymer based restorative product as suitable for restorations involving occlusal surfaces classed by Type 1, Class 2, Group 1 on ISO 4049.	
General Composition		- Bis-Gma[Bispenol A Glycerolate (1glycerol/ Phenol)dimethacrylate] - UDMA[Diurethane dimethacrylate] - Bis-Ema [Bisphenol A ethoxylate dimethacrylate] - TEGDMA[Tri(ethylene glycol)dimethacrylate] - TMPTMA[Trimethylol propane trimethacrylate] - GDMA[Glycerol dimethacrylate] - Camphorquinone	
Sensitivity of ambient light	Remain physically homogeneous	Physical homogeneity	Physical homogeneity
Compressive strength	Should be more than 5MPa.	Average 232.76 MPa	Average 288.68MPa
Flexural strength	> 80 MPa	Average 87MPa	91.82MPa
Intensity for curing	-	1000-1200 ㎽/㎠	-
Wavelength for curing	-	420-480nm	-
Depth of cure	> 1.0 mm	2.88mm	4.96 mm
Filler particle size distribution	-	Barium glass : 0.78 ㎛ Silica :16nm	-

Surface hardness (Vickers hardness)	-	Average 56KHN	Average 39.36KHN
Radio-opacity	> 1mm	More than 1mm	More than 1mm
Water sorption	< 40 $\mu g/mm^3$	2.97 $\mu g/mm^3$	13.78 $\mu g/mm^3$
Solubility	< 7.5 $\mu g/mm^3$	0.0 $\mu g/mm^3$	0.23 $\mu g/mm^3$
Release profile		This device did not contain fluoride or nitrate ions.	
Working time		This device is a light curing type product. (Working time test is applied for self-cured resin.)	
Curing time	-	20sec	-
Setting time		This device is a light curing type product. (Setting time test is applied for self-cured resin.)	
Shade and color stability	-	Consistency	Consistency
Shelf Life	-	3 years	3 years

Both subject and predicate devices have the same indications for use, principle of operation, Sensitivity of ambient light, radio opacity and shelf life. The physical properties of subject and predicate devices such as compressive strength, flexural strength, and solubility are all similar.

As depicted above, the values for the depth of cure, surface hardness and water sorption between the subject device and predicate device are different but the test results are within the range of the criteria of ISO standards such as ISO 4049 and ISO 6507 this difference does not affect the substantial equivalence.

Non-clinical Testing

The subject device was tested to the following standards:

- Biocompatibility Testing according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-11:2006.
- Physical properties testing and shelf life test according to ISO 4049:2009
- Surface hardness test according to ISO 6507-1:2005
- Compressive Strength Test according to ISO 3107:2011

The data analysed from the biocompatibility evaluation of the subject device, and the results of the biocompatibility tests according to ISO 10993 substantiate that the Nexcomp is substantially equivalent to the predicate device. The subject device is different from the predicate devices in that it contains the same key biocompatible ingredients, but in different proportions. The biocompatibility test report supports this difference and it does not affect the substantial equivalence.

Conclusion

The Subject Device, Nexcomp has been compared with its predicate, Nexcomp with regard to indications, performance data and chemical composition. The comparison shows that Nexcomp is substantially equivalent to the predicate device.