DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 17, 2015

Sybron Dental Specialties
Ms. Courtney Clark
Regulatory Affairs Manager
1717 W. Collins Avenue
Orange, CA 92867

Re: K151332
Trade/Device Name: Nexus Universal, Nexus Universal Chroma
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: May 18, 2015
Received: May 19, 2015

Dear Ms. Clark:

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,

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

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)* K151332

Device Name
Nexus Universal/ Nexus Universal Chroma

Indications for Use *(Describe)*
Nexus Universal/Nexus Universal Chroma is indicated for cementation of all indirect restorations including ceramic, resin, and metal-based inlays/onlays, crowns, bridges, posts, and veneers*. Additional indications include core build-ups and cementation of crowns to implants.
*Adhesive application on the preparation is required for veneer cementation using Nexus Universal and Nexus Universal Chroma.

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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SECTION 5. 510(k) SUMMARY for Nexus Universal / Nexus Universal Chroma

Nexus Universal /Nexus Universal Chroma

1. Submitter Information**:**

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687

Contact Person: Courtney Clark
Telephone Number: 714-516-7426
Fax Number: 714-516-7472

Date Prepared: May 18, 2015

2. Device Name:

- Proprietary Name: Nexus Universal and Nexus Universal Chroma
- Classification Name: Dental Cement w/out Zinc-Oxide Eugenol

  Cement, Dental

- CFR Number: 872.3275
- Device Class: II
- Product Code: EMA

3. Predicate Device:

The proposed Nexus Universal and Nexus Universal Chroma are substantially equivalent to the legally marketed predicate device, Maxcem 2 (K073209), cleared on January 29, 2008, product codes MZW, EMA.

4. Description of Device:

Nexus Universal / Nexus Universal Chroma is indicated for cementation of all indirect restorations including ceramic, resin, and metal-based inlays/onlays, crowns, bridges, posts, and veneers*. Additional indications include core build-ups and cementation of crowns to implants.
*Adhesive application on the preparation is required for veneer cementation using Nexus Universal and Nexus Universal Chroma.

Nexus Universal and Nexus Universal Chroma are offered in paste/paste formulations for use as self-etch, self-adhesive resin cements or as bonded resin cements. These cements are considered permanent and not temporary.

The dual-cure material is packaged in dual barrel syringes with single-use automix tips and optional curved dispensing tips to allow the user to deliver the desired volume of cement directly into the restoration and/or tooth preparation.

Accessories Used with Nexus Universal / Nexus Universal Chroma	**Manufacturer of Accessory**
Dual barrel syringe	Sulzer Mixpac AG Ruetistrasse 7 Haag Sankt gallen, Switzerland 9469
Curved dispensing tips	Sulzer Mixpac AG Ruetistrasse 7 Haag Sankt gallen, Switzerland 9469
Auto-mix tips	Sulzer Mixpac AG Ruetistrasse 7 Haag Sankt gallen, Switzerland 9469

Nexus Universal and Nexus Universal Chroma are offered in multiple shades. The difference between Nexus Universal and Nexus Universal Chroma is that Nexus Universal Chroma offers a gel-state color indicator, which visually displays the optimal time to remove the excess cement.

5. Statement of Indications for Use:

Nexus Universal/Nexus Universal Chroma is indicated for cementation of all indirect restorations including ceramic, resin, and metal-based inlays/onlays, crowns, bridges, posts, and veneers*. Additional indications include core build-ups and cementation of crowns to implants.

*Adhesive application on the preparation is required for veneer cementation using Nexus Universal and Nexus Universal Chroma.

6. Description of Substantial Equivalence:

Technological Characteristics

Nexus Universal and Nexus Universal Chroma, like their predicate Maxcem 2 (K073209), are self-adhesive paste/paste dual-cure permanent resin cements. They provide a simplified one-step cementation procedure by combining the etching, priming, bonding and cementing steps into a single step. This is achieved by incorporating adhesive monomers along with an acid tolerant redox initiator system into a traditional resin cement.

There are two curing mechanisms associated with the proposed Nexus Universal and Nexus Universal Chroma self-adhesive resin cements: self-curing (also referred to as dark-curing) mechanism by a redox initiator system and light-curing by a photoinitiator.

The proposed Nexus Universal and Nexus Universal Chroma offer the following changes over the predicate, Maxcem 2 (K073209):

1. A gel-state color indicator (Nexus Universal Chroma only) provides clinicians with a visual cue indicating the optimal timing to remove the gelled excess cement
2. Increased bond strength to dentin
3. Increased bond compatibility with adhesive even in self-cure mode (also referred to as dark-cure mode)

The proposed Nexus Universal Chroma has a gel-state indicator that is a redox color indicator that has an initial pink color for the mixed paste before gelation. The pink color will fade away once the mixed paste reaches the gel state, the ideal timing for removing excess cement. For both the Nexus Universal and Nexus Universal Chroma, the increased bond strength to dentin and the increased bond compatibility with the adhesive in self-cure mode is achieved by modifying the adhesive property of the resin matrix and wetting ability of the pastes along the acid tolerant redox initiator system used in the proposed.

Non-Clinical Performance Data

Non-clinical performance data included testing for bond strength to various substrates, radiopacity, film thickness, diametral strength, consistency, amount of heat generated during setting, water sorption, dark-cure bond compatibility, and gel-state indicator color transition.

Gel/set time testing and biocompatibility testing were also performed. The data analyzed from the various tests substantiate that the proposed Nexus Universal and Nexus Universal Chroma are substantially equivalent to the predicate, Maxcem 2 (K073209). The following standards were utilized for the non-clinical performance testing of the proposed:

- ISO 10993-1: 2009 Biological evaluation of medical devices
- ISO 10993-3:2003 Biological Evaluation of Medical Devices- Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-6:2007 Biological Evaluation of Medical Devices- Part 6: Tests for Local Effects after Implantation
- ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11: 2006 Biological Evaluation of Medical Devices- Part 11: Tests for System Toxicity
- ISO 4049: 2009 Dentistry – Polymer-Based Restorative Materials

Additional testing was performed as recommended by the following guidance document:

- FDA “Guidance for Industry and FDA Staff: Dental Cements – Premarket Notification”

Table 5.1: Predicate and Proposed Device Comparison Table

Element	Predicate Device- Maxcem 2	Nexus Universal/Nexus Universal Chroma, Dental Cement
510(k)	Maxcem 2 (K073209)	To be assigned
Trade Name	Maxcem 2, Dental Cement	Nexus Universal and Nexus Universal Chroma, Dental Cement
Target Users	Licensed dental professionals	Licensed dental professionals
Indications for Use	Maxcem 2 is intended for cementation of indirect restorations including ceramic, resin and metal-based inlays, onlays, crowns, bridges, posts, and veneers.* Additional indications include core-buildup material, pit and fissure sealant, and cementation of crown restorations to implants. *Adhesive application on the prep is required for veneer cementation using Maxcem 2.	Nexus Universal/Nexus Universal Chroma is indicated for cementation of all indirect restorations including ceramic, resin, and metal-based inlays/onlays, crowns, bridges, posts, and veneers*. Additional indications include core build-ups and cementation of crowns to implants. *Adhesive application on the preparation is required for veneer cementation using Nexus Universal and Nexus Universal Chroma.
Common Name	Dental Cement	Dental Cement
Classification Name	Cement, Dental, per 21 CFR § 872.3275(b)	Cement, Dental, per 21 CFR § 872.3275(b)
Class	II	II
Product Code	MZW/EMA	MZW/EMA
Storage	Ambient Temperature	Ambient Temperature
Curing Mechanism	Photo initiation or self-cure	Photo initiation or self-cure
Material Compatibility	Biocompatibility meets requirements	Biocompatibility meets requirements
Shelf Life	18 months based on real time data	18 months based on accelerated data
Gel/Set Time (fresh ambient/ fresh oral)	≥ 2’00” / ≤ 3’30”	≥ 2’00” / ≤ 3’30”
Bond Strength to Dentin	20.35 MPa	23.05 MPa
Bonding strength for Post Cementation	59.68 lbs	62.34 lbs
Radiopacity, % aluminum	280%	283%
Film Thickness (µm)	22 µm	24 µm
Diametral Strength, Mpa (Dual-Cure mode)	54.8 MPa	58.1 MPa
Consistency	3.00 cm	3.39 cm
Maximum Temperature During Self Curing	N/A	26.89°C

Water sorption	N/A	33.5 µg/mm^3
Color indicator version (Nexus Universal Chroma):		
Color at set time	N/A	Pass

Clinical Performance Data

Clinical performance testing has not been performed for the proposed devices.

Conclusion as to Substantial Equivalence

The slight modifications to the formula of the predicate, Maxcem 2 (K073209), to increase bond strength and bond compatibility with the adhesive in self-cure mode, and add the gel-state color indicator (Nexus Universal Chroma only) shall not affect the safety or efficacy of the proposed devices based on internal performance testing and biocompatibility testing. Nexus Universal and Nexus Universal Chroma are substantially equivalent to the predicate, Maxcem 2 (K073209), based on formulation, performance and testing comparisons.