January 19, 2023

No Stress Impress LLC
% Cheryl Wagoner
Consultant
Wagoner Consulting LLG
5215 Crosswinds Drive
Wilmington, North Carolina 28409

Re: K213175
Trade/Device Name: No Stress Impress
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: December 6, 2022
Received: December 7, 2022

Dear Cheryl Wagoner:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K213175

Device Name
No Stress Impress

Indications for Use *(Describe)*

No Stress Impress is intended for use as a rebasing and relining impression material as well as for general impressions including but not limited to dentures, root surfaces, and posts.

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
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*"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
(as required by 21 CFR 807.92)

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|---|---|
| Submitter | No Stress Impress |
| Contact Person | Misael Otero, DDS<br>President, No Stress Impress<br>2012 Scrimshaw Place<br>Wilmington, North Carolina 28405<br>917-304-7010 |
| Date Prepared | April 25, 2022 |

| | |
|---|---|
| Trade Name | No Stress Impress |
| Common Name | Impression material |
| Classification | 21 CFR §872.3660, Product Code ELW |
| Class | Class II |

| **Product name** | **Manufacturer** | **510(k) #** | **Basis for Substantial Equivalence** |
|---|---|---|---|
| **Primary Predicate** | | | |
| Impression Compound | Sybron Dental Specialties (acquired by KavoKerr) | K110378 | • Same intended use<br>• Same Indications<br>• Similar technology |

| | |
|---|---|
| Description | No Stress Impress is a thermoplastic impression material available for full or partial impressions that comes as a stick or wafer. |

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|---|---|
| Intended Use/Indications for Use | No Stress Impress is intended for use as a rebasing and relining impression material as well as for general impressions including but not limited to dentures, root surfaces, and posts. |

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|---|---|
| Technological Characteristics | This product is made ingredients similar to ingredients found in other impression materials currently on the U.S. markets and substantially equivalent to the predicate devices. |

<table>
<tr><td>Performance Data</td><td>Material testing per ISO 4823:2015, 7.8 Dentistry Elastomeric Material was conducted with satisfactory results.<br><br>Biocompatibility testing was performed in accordance with ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing” including:<br><br>
<table>
<tr><th>Test Performed</th><th>Results</th></tr>
<tr><td>ISO Oral Mucosal Irritation Study in Hamsters -<br>Collar Method - 24 hours</td><td>Non-irritating</td></tr>
<tr><td>ISO Guinea Pig Maximization Sensitization Test</td><td>Non-sensitizing</td></tr>
<tr><td>Cytotoxicity Study Using the ISO Elution Method</td><td>No lysis, no reactivity, no pH shift</td></tr>
<tr><td>Cytotoxicity Study Using the ISO Agarose Overlay Method</td><td>No lysis, no reactivity</td></tr>
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|---|---|
| Conclusion | The Subject device has identical intended use and indications as the primary predicate. The ingredients are similar to the predicate. The labeling claims of the Subject device are the similar to those of the predicate.<br><br>The labeling of the Subject device contains the similar warnings and precautions as those in the labeling of the predicates.<br><br>Any differences that exist between the Subject device and the predicates have no significant effect on the safety or effectiveness.<br><br>The Subject device is substantially equivalent to other prescription impression materials cleared in the US in terms of biocompatibility, technology, intended use, indications, and suitability characteristics. |