December 15, 2022

Genoss Co., Ltd.
Woojung Park
Staff
1F, Gyeonggi R&DB Center, 105 Gwanggyo-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do 16229
Korea, South

Re: K214086
Trade/Device Name: Bright Impress-Light, Bright Impress-Medium, Bright Impress-Heavy, Bright Impress-Bite, Bright Impress-Putty
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: November 16, 2022
Received: November 16, 2022

Dear Woojung Park:

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)*
K214086

Device Name
Bright Impress - Light, Bright Impress - Medium, Bright Impress - Heavy, Bright Impress - Putty, Bright Impress - Bite

Indications for Use *(Describe)*
Impression of inlay, onlay crown, and bridge preparation
- Crown, bridge impression
- Inlay and onlay impression
- Functional impression
- Denture impression
- Study model impression

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.

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510(k) Summary K214086

12/11/2021

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	1F, Gyeonggi R&DB Center / 226, 2F, GSBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Phone/Fax	+82-70-7098-8938/ +82-31-888-5105
Contact person	Woojung Park / RA wjpark@genoss.com
Summary Date	12/11/2021

2. Device Name

Proprietary name:	Bright Impress – Light, Bright Impress – Medium, Bright Impress – Heavy, Bright Impress – Putty, Bright Impress – Bite
Regulation description:	Impression Material
Classification name:	Dental Impression Material
Common Name:	Material, Impression

3. Predicate Device

K170736	Hysil Impression Materials

4. Description

Bright Impress impression material is a fast-set of addition-reaction silicone elastomer (Vinyl polysiloxane)-based material for dental professionals, consisting of five types (Light, Medium, Heavy, Bite and Putty) with superior hydrophilicity, dimensional accuracy, high tensile strength, and resistant to deformation. It is designed for versatile impression techniques of crowns, bridges, orthodontics and implants.

5. Technological Characteristics

Bright Impress was compared with the predicate device 'HySil Impression Material' in clinical, technical, biological view. The characteristics that differed from the predicate device were performed by gap analysis, which confirmed equivalence with the predicate device. Technological characteristics of Bright Impress and HySil Impression Material are as following;

5.1 **Bright Impress – Heavy, Bright Impress – Medium, Bright Impress – Light, Bright Impress – Putty**

Device name		**Bright Impress-Heavy, Bright Impress-Medium, Bright Impress-Light, Bright Impress-Putty**	**HySil-Heavy, Mono, Light, Putty**
Manufacture		Genoss Co.,Ltd.	Osstem Implant Co., Ltd.
510(K) Number		New device	K170736
Clinical	**Target population**	Human tooth	Human tooth
	Indication for use	Impression of inlay, onlay crown, and bridge preparation - Crown, bridge impression - Inlay and onlay impression - Functional impression - Denture impression - Study model impression	HySil Putty is to be used as preliminary materials for: - Two-step Putty-wash impression technique - One-step Putty-wash impression technique HySil Heavy is to be used as heavy-bodies materials for: - One-step impression technique (simultaneous technique) using single or dual viscosities - Two-step impression technique using dual viscosities - Functional impression HySil Mono is to be used as a medium-bodies tray or syringeable impression material for: - Taking impressions over fixed / removable restorations and implants (i.e., transferring impression posts and bridge components) - Functional impression

						- Fabricating full or partial dentures - Reline impressions - Use in the simultaneous mixing technique as well as the putty-wash and triple tray techniques - Transferring root posts when fabricating posts and cores indirectly HySil Light is to be used as syringeable impression materials for: - Two-step putty-wash impression technique - One-step putty-wash impression technique - Two-step impression technique using dual viscosities - Reline impression - Fabricating full or partial dentures			
	Site of application	Human teeth				Human teeth			
Technical	**Type**	Light	Medium	Heavy	Putty	Light	Mono	Heavy	Putty
	Type of ISO4832	3	2	1	0	3	2	1	0
	Working Time	126sec	117sec	112sec	-	2.850 min	2.612 min	2.022 min	
	Mixing Time	-	-	-	30sec	-	-	-	38sec
	Consistency	42.7mm	39.0mm	27.0mm	26.0mm	45.60 mm	35.65 mm	28.47 mm	31.27 mm
	Compatibility with Gypsum	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Linear Dimensional change	0.15%	0.18%	0.0%	0.07%	0.03%	0.02%	0.02%	0.031%
	Elastic recovery	98.48%	99.18%	99.00%	97.98	98.7%	98.6%	98.8%	99.8%
	Strain-in compression	2.54%	2.26%	1.7%	1.06%	2.30%	3.00%	2.30%	1.6%
Biological	**Material**	Polyvinyl Siloxane				Polyvinyl Siloxane			
	Chemical Safety	Biocompatible				Biocompatible			
	Sterilization	Non sterile				Non sterile			

5.2 Bright Impress – Bite

Device name		Bright Impress-Bite	HySil-Bite
Manufacture		Genoss Co.,Ltd.	Osstem Implant Co., Ltd.
510(K) Number		New device	K170736
Clinical	Target population	Human tooth	Human tooth
	Indication for use	Impression of inlay, onlay crown, and bridge preparation - Crown, bridge impression - Inlay and onlay impression - Functional impression - Denture impression - Study model impression	HySil Bite is used for impression as below: - Taking occlusal surfaces - confirming occlusal surfaces - Recording after putting the articulator
	Site of application	Human teeth	Human teeth
Technical	Working Time	Pass	Pass
	Minimum residence time in the mouth	≤ 90sec	≤ 90sec
	Hardness	≥ 20HD	50 HD
	Flexural Strength	Pass	Pass
	Recovery after deformation	< 0.1mm	< 0.1mm
	Linear Dimensional change	≤ 1.5%	-0.16 %
Biological	Material	Polyvinyl Siloxane	Polyvinyl Siloxane
	Chemical Safety	Biocompatible	Biocompatible
	Sterilization	Non sterile	Non sterile

6. Indication for use

Impression of inlay, onlay crown, and bridge preparation
- Crown, bridge impression
- Inlay and onlay impression
- Functional impression
- Denture impression
- Study model impression

7. Biocompatibility Data

Biocompatibility testing on the proposed Bright Impress has been completed. Requirements for biological evaluation of the proposed device were based on FDA recognized concensus standard of ISO10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological bone and tissues with its intended use. The following biocompatibility tests were completed:

7.1 Bright Impress - Light

(P: Pass, F: Fail)

No.	Test	Method	Acceptance criteria	P/F	Report No.
1	Cytotoxicity (MEM Test)	ISO 10993-05	None cytotoxicity	P	MGK-2022-001757
2	Sensitization	ISO 10993-10	None sensitization	P	MTK-2019-000355
3	Irritation or intracutaneous reactivity	ISO 10993-10	None irritation	P	MTK-2019-000355
4	Systemic toxicity(acute)	ISO 10993-11	None systemic toxicity	P	MTK-2019-000355

7.2 Bright Impress - Medium

(P: Pass, F: Fail)

No.	Test	Method	Acceptance criteria	P/F	Report No.
1	Cytotoxicity (MEM Test)	ISO 10993-05	None cytotoxicity	P	MGK-2022-001756
2	Sensitization	ISO 10993-10	None sensitization	P	MTK-2019-000357
3	Irritation or intracutaneous reactivity	ISO 10993-10	None irritation	P	MTK-2019-000357
4	Systemic toxicity(acute)	ISO 10993-11	None systemic toxicity	P	MTK-2019-000357

7.3 Bright Impress - Heavy

(P: Pass, F: Fail)

No.	Test	Method	Acceptance criteria	P/F	Report No.
1	Cytotoxicity (MEM Test)	ISO 10993-05	None cytotoxicity	P	MGK-2022-001758
2	Sensitization	ISO 10993-10	None sensitization	P	MTK-2018-000723
3	Oral Mucosa Irritation	ISO 10993-10	None irritation	P	MTK-2018-000724

7.4 Bright Impress - Putty

(P: Pass, F: Fail)

No.	Test	Method	Acceptance criteria	P/F	Report No.
1	Cytotoxicity (MEM Test)	ISO 10993-05	None cytotoxicity	P	MGK-2022-001755
2	Sensitization	ISO 10993-10	None sensitization	P	MTK-2019-000359
3	Irritation or intracutaneous reactivity	ISO 10993-10	None irritation	P	MTK-2019-000359
4	Systemic toxicity(acute)	ISO 10993-11	None systemic toxicity	P	MTK-2019-000359

7.5 Bright Impress - Bite

(P: Pass, F: Fail)

No.	Test	Method	Acceptance criteria	P/F	Report No.
1	Cytotoxicity (MEM Test)	ISO 10993-05	None cytotoxicity	P	MGK-2022-001759
2	Sensitization	ISO 10993-10	None sensitization	P	MTK-2019-000327
3	Irritation or intracutaneous reactivity	ISO 10993-10	None irritation	P	MTK-2019-000326
4	Systemic toxicity(acute)	ISO 10993-11	None systemic toxicity	P	MTK-2019-000328

8. Performance Data

The proposed Bright Impress was evaluated using the following performance bench testing to confirm the performance characteristics:

8.1 Bright Impress - Light

No.	Items	Properties	Method	Doc No.
1	Visual	No substance material	Visual inspection	제19-02-019호
2	Volume	Size error of Standard Size < ±5%	Electronic Scale	
3	Package	No damage	Visual Inspection	
4	Color	Contrasting color of base and catalyst	Visual Inspection	
5	Consistency	≥ 36mm	ISO 4823	
6	Working Time	≥ 120 sec	ISO 4823	
7	Detail reproduction	20㎛ reproduction without interruption	ISO 4823	
8	compatibility with gypsum	50㎛ reproduction without interruption	ISO 4823	
9	Linear Dimensional change	≤ 1.5%	ISO 4823	
10	Elastic recovery	≥ 96.5%	ISO 4823	
11	Strain in compression	2.0~20%	ISO 4823	

8.2 Bright Impress – Medium

No.	Items	Properties	Method	Doc No.
1	Visual	No substance material	Visual inspection	제19-02-022호
2	Volume	Size error of Standard Size < ±5%	Electronic Scale	
3	Package	No damage	Visual Inspection	
4	Color	Contrasting color of base and catalyst	Visual Inspection	
5	Consistency	31mm~41mm	ISO 4823	
6	Working Time	≥ 90 sec	ISO 4823	
7	Detail reproduction	20㎛ reproduction without interruption	ISO 4823	
8	compatibility with gypsum	50㎛ reproduction without interruption	ISO 4823	
9	Linear Dimensional change	≤ 1.5%	ISO 4823	
10	Elastic recovery	≥ 96.5%	ISO 4823	
11	Strain in compression	2.0~20%	ISO 4823	

8.3 Bright Impress – Heavy

No.	Items	Properties	Method	Doc No.
1	Visual	No substance material	Visual inspection	CDM-18-0065
2	Capacity	Size error of Standard Size < ±5%	Electronic Scale	
3	Package	No damage	Visual Inspection	
4	Component Colour	Contrasting color of base and catalyst	Visual Inspection	
5	Consistency	≤ 35mm	ISO 4823	
6	Working Time	≥ 60 sec	ISO 4823	
7	Detail Reproduction	50㎛ reproduction without interruption	ISO 4823	
8	Compatibility with Cypsum	50㎛ reproduction without interruption	ISO 4823	
9	Linear Dimensional Change	≤ 1.5%	ISO 4823	
10	Elastic Recovery	≥ 96.5%	ISO 4823	
11	Strain-in-compression	0.8~20%	ISO 4823	

8.4 Bright Impress – Putty

No.	Items	Properties	Method	Doc No.
1	Visual	No substance material	Visual inspection	제19-02-016호
2	Volume	Size error of Standard Size < ±5%	Electronic Scale	
3	Package	No damage	Visual Inspection	
4	Color	Contrasting color of base and catalyst	Visual Inspection	
5	Consistency	≤ 35mm	ISO 4823	
6	Working Time	≤ 30 sec	ISO 4823	
7	Detail reproduction	75㎛ reproduction without interruption	ISO 4823	
8	compatibility with gypsum	75㎛ reproduction without interruption	ISO 4823	
9	Linear Dimensional change	≤ 1.5%	ISO 4823	
10	Elastic recovery	≥ 96.5%	ISO 4823	
11	Strain in compression	0.8~20%	ISO 4823	

8.5 Bright Impress – Bite

No.	Items	Properties	Method	Doc No.
1	Visual	No substance material	Visual inspection	제19-02-045호
2	Volume	Size error of Standard Size < ±5%	Electronic Scale	
3	Package	No damage	Visual Inspection	
4	Color	Contrasting color of base and catalyst	Visual Inspection	
5	Working Time	≤ 30 sec	DIN 13903	
6	Minimum residence time in the mouth	≤ 90sec	DIN 13903	
7	Hardness	≥ 20HD	DIN 13903	
8	Flexural Strength	≥ 8.0N	DIN 13903	
9	Recovery after deformation	< 0.1mm	DIN 13903	
10	Linear Dimensional change	≤ 1.5%	DIN 13903	

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Bright Impress met the established specifications necessary for consistent performance according to its intended use.

9. Conclusion

Based on the information provided in this premarket notification of GENOSS Co., Ltd. concluded that Bright Impress is acceptable and safe, substantially equivalent to predicate device.