May 5, 2020

Lascod Spa
% Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K201184
Trade/Device Name: Lascod Impression Materials
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression material
Regulatory Class: Class II
Product Code: ELW
Dated: April 28, 2020
Received: May 1, 2020

Dear Dave Yungvirt:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201184

Device Name
Lascod Impression Materials

Indications for Use *(Describe)*
The Lascod family of silicone impression materials includes the brand names: Ghenesyl, Kromopan Sil are used by dentists to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define required interventions, and/or check their effectiveness.

The Ghenesyl Putty and Kromopan Sil Putty products are indicated for obtaining preliminary impressions for the two-step putty/wash and base for the sandwich technique. The impression can be electroplated.

The Ghenesyl Body and Kromopan Sil Body products are indicated for the two-step putty/wash and for the sandwich technique. The impression can be electroplated.

The Ghenesyl Mono and Kromopan Sil mono products are indicated for monophasic technique, though it can be used also with Super Light Body / Light Body / Regular Body wash silicones as support material inside individual impression tray or standard stainless-steel impression tray.

Kromopan Sil Bite and Oklurest used by dentists to take impressions of occlusal surfaces in order to confirm the occlusal surfaces onto the plaster models assembled on an articulator.

Kromopan Sil Bite and Oklurest and products are indicated for orthodontic occlusion registration, registration keys for gnathological registrations, inter-maxillary registration keys for centered positions, eruptions and ectopic eruptions, registration for cephalometric analysis which also require subsequent scanning with CAD systems.

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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510k Summary

1. Date — April 29, 2020

2. Submitter

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5. Predicate Device

510k number	K170736
Common Name	Impression Material
Classification Name	Material, Impression
Regulation Number	21 CFR 872.3660
Device Classification	Class II
Product Code	ELW

6. Indications for Use

The Lascod family of silicone impression materials includes the brand names: Ghenesyl, Kromopan Sil are used by dentists to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define required interventions, and/or check their effectiveness.

The Ghenesyl Putty and Kromopan Sil Putty products are indicated for obtaining preliminary impressions for the two-step putty/wash and base for the sandwich technique. The impression can be electroplated.

The Ghenesyl Body and Kromopan Sil Body products are indicated for the two-step putty/wash and for the sandwich technique. The impression can be electroplated.

The Ghenesyl Mono and Kromopan Sil mono products are indicated for monophasic technique, though it can be used also with Super Light Body / Light Body / Regular Body wash silicones as support material inside individual impression tray or standard stainless-steel impression tray.

Kromopan Sil Bite and Oklurest used by dentists to take impressions of occlusal surfaces in order to confirm the occlusal surfaces onto the plaster models assembled on an articulator.

Kromopan Sil Bite and Oklurest and products are indicated for orthodontic occlusion registration, registration keys for gnathological registrations, inter-maxillary registration keys for centered positions, eruptions and ectopic eruptions, registration for cephalometric analysis which also require subsequent scanning with CAD systems.

7. Device Description
   Lascod Impression Materials are addition-curing polyvinylsiloxane silicones. They exhibit excellent accuracy, maximum thixotropy, and hydrophilicity. Additional elastomeric properties include, fast in the mouth setting time, high resistance to tear, dimensional accuracy, and resistance to permanent deformation. The Lascod impression material product line boasts multiple different variants: hard and soft putty; heavy, regular, light and superlight body – all putties and bodies, are available both as normal and fast set; mono and bite. Putties are provided in 300 or 150 ml plastic jars. The body and the bite product lines, are usually offered in the standard (1: 1) 50 ml dual barrel cartridges. The Mono product line is provided in two forms; a standard (1: 1) 50 ml dual cartridge, and a (5: 1) 380 ml, large dual cartridge.

8. Performance testing and Shelf Life
   Lascod Impression Materials have been tested and are compliant with the requirements of ISO 4823:2015 “Dentistry Elastomeric Impression Materials.” Shelf Life testing demonstrated that the silicones could be stored for three years. The performance requirements that Lascod Silicones comply with are provided in Table 1.

9. Biocompatibility testing
   The FDA guidance "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" was used to determine biocompatibility testing requirements. Cytotoxicity, Irritation, and Sensitization testing conducted* demonstrate that the Lascod Impression Materials are biocompatible.

10. Substantial Equivalence
    Lascod Impression Materials have identical intended use and highly similar indications for use as the predicate device. Biocompatibility testing demonstrated that both predicate and subject devices were safe for intended use. Performance testing demonstrated that both subject

and predicate device complied with requirements of ISO 4823:2015 and are effective for the stated intended use. Based on the information presented above Lascod concludes that the Lascod Impression Materials are substantially equivalent to HySil Silicones.

Table 1: Substantial Equivalence

Descriptive information	**Predicate**	**Lascod Impression Material**
Company	Osstem Implant Co., Ltd.	Lascod Spa
Device Name	HySil Impression Material	Lascod Impression Material
510k number	K170736	N/A
Classification	II	II
Regulation	21 CFR 872.3660	21 CFR 872.3660
Descriptive information	**Predicate**	**Lascod Impression Material**
Product Code	ELW	ELW
Intended Use	To be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of patient's teeth and gums. To provide models for study and for production of restorative prosthetic devices.	The Lascod impression materials includes the brand names: Ghenesyl, Kromopan Sil are used by dentists to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define required interventions, and/or check their effectiveness. Kromopan Sil Bite and Oklurest used by dentists to take impressions of occlusal surfaces in order to confirm the surfaces onto the plaster models assembled on an articulator. The impression taken with Oklurest and/or Kromopan Sil can be scanned and used for occlusal surfaces registration and other diagnostic evaluation with CAD systems.
Indications for Use	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-bodied materials for: • One-step impression technique (simultaneous technique) using single or dual viscosities • Two-step impression technique using dual viscosities • Functional impressions HySil Mono is to be used as a medium-bodied tray or syringeable impression material for:	The Lascod impression materials includes the brand names: Ghenesyl, Kromopan Sil are used by dentists to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define required interventions, and/or check their effectiveness. The Ghenesyl Putty and Kromopan Sil Putty products are indicated for obtaining preliminary impressions for the two-step putty/wash and base for the sandwich technique. The impression can be electroplated. The Ghenesyl Body and Kromopan Sil Body products are indicated for the two-step putty/wash and for the sandwich technique. The impression can be electroplated.

	• Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components) • Functional impressions • Fabricating crown and bridgework or inlays • 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 impressions • Fabricating full or partial dentures HySil Extra 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 impressions • Fabricating full or partial dentures HySil Bite is used for impression as below. • Taking occlusal surfaces	The Ghenesyl Mono and Kromopan Sil mono products are indicated for monophasic technique, though it can be used also with Super Light Body / Light Body / Regular Body wash silicones as support material inside individual impression tray or standard stainless-steel impression tray. Kromopan Sil Bite and Oklurest used by dentists to take impressions of occlusal surfaces in order to confirm the occlusal surfaces onto the plaster models assembled on an articulator. Kromopan Sil Bite and Oklurest and products are indicated for for orthodontic occlusion registration, registration keys for gnathological registrations, inter-maxillary registration keys for centered positions, eruptions and ectopic eruptions, registration for cephalometric analysis which also require subsequent scanning with CAD systems.
Materials	Vinylpolysiloxane	Vinylpolysiloxane
Performance Testing		
Standard	ISO 4823:2015	ISO 4823:2015
Type	Type 0 and Type 3	Type 0, 1, 2 and 3
Consistency	Pass	Pass
Working time	Pass	Pass
Mixing time	Pass	Pass
Detail Reproduction	Pass	Pass

Compatibility with Gypsum	Pass	Pass
Linear Dimensional Change	Pass	Pass
Elastic Recovery	Pass	Pass
Strain in Compression	Pass	Pass
Shore A Hardness	Pass	Pass
Shelf Life	3 Years	3 Years
Biocompatibility	ISO 10993	ISO 10993
Cytotoxicity	Pass	Pass
Irritation	Pass	Pass
Sensitization	Pass	Pass

11. Conclusion:

Comparison results demonstrate that the specifications and performance of the device are same as the legally marketed predicate device.

Based on the same intended use, similar indications for use, technological characteristics, and chemical properties between HySil Silicones and Lascod Silicones, Lascod concludes that Lascod Impression Materials are substantially equivalent to HySil Silicones.