October 31, 2025

Vigodent Indústria e Comercio Ltda
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K253501
Trade/Device Name: Hydro Print Premium Fast Set - 454g (1lb) (052037); Hydro Print Premium Regular Set - 454g (1lb) (052327); Chroma Print Premium Fast Set - 454g (1lb) (052457); Chroma Print Premium Regular Set - 454g (1lb) (051460); Perfil Pro - 454g (1lb) (056213); Perfil Pro+ - 454g (1lb) (056121); Perfil Pro Chroma - 454g (1lb) (056122); Hydro Print Premium Fast Set - Multi Pack (056205); Hydro Print Premium Regular Set - Multi Pack (056208); Hydro Print Premium Fast Set - 9,07Kg (20lb) (056204); Hydro Print Premium Regular Set - 9,07Kg (20lb) (056207)
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression material
Regulatory Class: Class II
Product Code: ELW
Dated: October 30, 2025
Received: October 30, 2025

Dear Prithul Bom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

Please provide the device trade name(s).

Hydro Print Premium Fast Set - 454g (1lb) (052037);
Hydro Print Premium Regular Set - 454g (1lb) (052327);
Chroma Print Premium Fast Set - 454g (1lb) (052457);
Chroma Print Premium Regular Set - 454g (1lb) (051460);
Perfil Pro - 454g (1lb) (056213);
Perfil Pro+ - 454g (1lb) (056121);
Perfil Pro Chroma - 454g (1lb) (056122);
Hydro Print Premium Fast Set - Multi Pack (056205);
Hydro Print Premium Regular Set - Multi Pack (056208);
Hydro Print Premium Fast Set - 9,07Kg (20lb) (056204);
Hydro Print Premium Regular Set - 9,07Kg (20lb) (056207)

Please provide your Indications for Use below.

CHROMA PRINT PREMIUM REGULAR AND FAST SET:
Indications:
Chroma Print Premium is indicated for total or partial impressions of dentate or edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

HYDRO PRINT PREMIUM REGULAR AND FAST SET
Indications:
Hydro Print Premium is indicated for total or partial impressions of dentate or edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

PERFIL PRO
Indications:
Perfil Pro is indicated for total or partial impressions of dentate and edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

PERFIL PRO CHROMA
Indications:
Perfil Pro Chroma is indicated for total or partial impressions of dentate and edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

PERFIL PRO +
Indications:
Perfil Pro+ is indicated for total or partial impressions of dentate and edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-10-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vigodent Indústria e Comercio Ltda
Applicant Address	Rua Pesqueira 26 Rio de Janeiro RJ 21041-150 Brazil
Applicant Contact Telephone	+5521984956266
Applicant Contact	Ms. Catia Mara da Eira Hoehn
Applicant Contact Email	choehn@vigodent.com.br

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hydro Print Premium Fast Set - 454g (1lb) (052037); Hydro Print Premium Regular Set - 454g (1lb) (052327); Chroma Print Premium Fast Set - 454g (1lb) (052457); Chroma Print Premium Regular Set - 454g (1lb) (051460); Perfil Pro - 454g (1lb) (056213); Perfil Pro+ - 454g (1lb) (056121); Perfil Pro Chroma - 454g (1lb) (056122); Hydro Print Premium Fast Set - Multi Pack (056205); Hydro Print Premium Regular Set - Multi Pack (056208); Hydro Print Premium Fast Set - 9,07Kg (20lb) (056204); Hydro Print Premium Regular Set - 9,07Kg (20lb) (056207)
Common Name	Impression material
Classification Name	Material, Impression
Regulation Number	872.3660
Product Code(s)	ELW, N/A: NO ADDITIONAL ASSOCIATED PRODUCT CODES ARE APP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K160097	Image Alginate	ELW
K160441	KromaFaze Alginate	ELW

Device Description Summary

21 CFR 807.92(a)(4)

Device Description – Principle of Operation

The Vigodent Alginate Impression Materials are irreversible hydrocolloid powders intended to be mixed with water to form a paste that sets by gelation. The material is placed in a standard dental impression tray and introduced into the patient's oral cavity to capture the anatomical details of teeth and soft tissues. Once set, the impression is removed from the mouth and poured with dental gypsum to obtain a working model.

Conditions of Use

The products are used in dental clinics and laboratories for total or partial impressions in the fabrication of study models, provisional prostheses, orthodontic appliances, and other preliminary dental applications. The device directly contacts the oral cavity tissues for a short duration (minutes) and does not remain in the body.

Interaction with Patient and Other Devices
The alginate material only interacts with oral tissues during impression taking and does not require any surgical procedure. The material interfaces with standard dental trays and dental gypsum products, with which it is compatible. No electronic components, implants, or additional medical devices are involved.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

CHROMA PRINT PREMIUM REGULAR AND FAST SET:
Indications:
Chroma Print Premium is indicated for total or partial impressions of dentate or edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

HYDRO PRINT PREMIUM REGULAR AND FAST SET
Indications:
Hydro Print Premium is indicated for total or partial impressions of dentate or edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

PERFIL PRO
Indications:
Perfil Pro is indicated for total or partial impressions of dentate and edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

PERFIL PRO CHROMA
Indications:
Perfil Pro Chroma is indicated for total or partial impressions of dentate and edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of single and multiple restorations, crowns, and fixed bridges.

PERFIL PRO +
Indications:
Perfil Pro+ is indicated for total or partial impressions of dentate and edentulous mouths in the fabrication of complete and partial removable dentures, orthodontic study models, and impressions for the manufacture of
single and multiple restorations, crowns, and fixed bridges.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject devices are identical to those of the predicate devices (Image Alginate, K160097, and KromaFaze Alginate, K160441). All devices are dental impression materials intended for making total or partial impressions in the fabrication of study models, provisional prostheses, orthodontic appliances, and other preliminary dental applications.
The technological characteristics of the subject devices are also consistent with the predicates. All are irreversible hydrocolloid (alginate) powders that are mixed with water to form an impression material. Minor differences exist, such as the inclusion of a chromatic phase indicator (Chroma Print and Perfil Chroma) and variations in setting time (regular vs. fast set). These differences are not critical to the intended use and do not raise new questions of safety or effectiveness.
Performance testing conducted in accordance with ISO 21563 confirmed compliance with requirements for working time, setting time, elastic recovery, detail reproduction, compatibility with gypsum, and compressive strength. A biological risk assessment performed in accordance with ISO 10993-1 confirmed the devices are biocompatible and safe for their intended clinical use.

Technological Comparison

21 CFR 807.92(a)(6)

The subject devices (Vigodent Alginate Impression Materials) share the same fundamental technological characteristics as the identified predicates, Image Alginate (K160097) and KromaFaze Alginate (K160441). All devices are irreversible hydrocolloid (alginate) dental impression materials supplied as powders to be mixed with water chairside, forming an elastic gel by alginate gelation. The design, principle of operation, clinical application, and professional use are the same across subject and predicate devices.
Regarding material/chemical composition, the subject and predicate devices are based on alginate salts with calcium sulfate, phosphate retarders, siliceous fillers (e.g., diatomaceous earth), and minor additives (e.g., pigments/aroma). The Vigodent products include minor formulation adjustments (e.g., indicator dyes for chromatic variants; fast vs. regular setting) that do not change the fundamental technology or clinical performance.
Performance: Testing in accordance with ISO 21563 demonstrated conformity for working/setting time, elastic recovery, detail reproduction, compatibility with gypsum, and compressive strength.
Biocompatibility: As surface-contacting, limited-duration devices (oral mucosa ≤24 h), biological safety was demonstrated per ISO

10993-1 via a toxicological risk assessment of raw materials and device category; no new biological risks are introduced relative to the predicates.
Conclusion: Any differences (e.g., indicator dye presence; regular vs. fast set) are minor, not critical to intended use, and do not raise new questions of safety or effectiveness. Therefore, the subject devices are substantially equivalent to Image Alginate (K160097) and KromaFaze Alginate(K160441) under 21 CFR 872.3660 (ELW).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing was conducted to evaluate the performance of Vigodent alginates in accordance with ISO 21563 (Hydrocolloid impression materials. Tests included setting time, mixing time, detail reproduction, elastic recovery, compressive strength, dimensional stability, and compatibility with dental gypsum. All results met the acceptance criteria specified in the applicable standard, demonstrating that the products are safe and effective for their intended use.
No animal or clinical testing was conducted. According to ISO 10993, biological evaluation was performed through a toxicological risk assessment approach and review of historical safe use of the materials. Furthermore, substantial equivalence is supported by predicate devices Image Alginate (K160097) and KromaFaze Alginate (K160441), which share similar composition, intended use, and patient contact.

Not Applicable. Clinical data were not necessary to support the substantial equivalence determination for this device.

The Vigodent alginate impression materials have been legally marketed in Brazil for more than 10 years, with valid registrations at ANVISA (Brazilian Health Regulatory Agency). Throughout this commercialization period, no adverse events or significant safety concerns have been reported. This conclusion is supported by technovigilance reports and customer complaint records, which show no critical incidents or risks to patient health.
Although the Perfil Pro line is more recent, it is manufactured with the same raw materials, formulation principles, and technology as Hydro Print Premium and Chroma Print Premium alginates, which are well established and consolidated in the Brazilian market for over a decade. The only relevant modification is the use of a green pigment, classified as food-grade, which was specifically included in the biological evaluation. The biological evaluation demonstrated satisfactory results regarding both safety and effectiveness, confirming that the Vigodent alginates do not pose biocompatibility concerns.
The devices comply with the requirements of ISO 21563 (Dentistry — Hydrocolloid impression materials) and demonstrate substantial equivalence to the selected predicate devices. Given the long history of safe clinical use in Brazil, absence of adverse event reports, results of the biological evaluation, and conformity with ISO 21563, no additional clinical testing was deemed necessary for this submission.
Therefore, the subject device can be considered as safe, effective, and performing as well as the legally marketed predicate devices.