July 2, 2026

Avinent Implant System S.L.U.
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K260527
Trade/Device Name: FACE4D Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 21, 2026
Received: May 26, 2026

Dear Angela Blackwell:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K260527

Please provide the device trade name(s).

FACE4D Aligner

Please provide your Indications for Use below.

FACE4D aligners are indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars).

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)

FACE4D
510K Summary
May 19, 2026

Name and Address: Avinent Implant System S.L.U.
Carretera de Navarcles, 107 Pol. Ind. Santa Anna I
Santpedor
Barcelona, Spain 08251
Contact Person: Anna Cortina
Email: annacortina@avinent.com
Telephone: +34 938 273465

Name of device: FACE4D
Common name: Sequential aligners
Classification Name: Orthodontic Plastic Bracket
CFR: 21 CFR 872.5470
Primary Product Code: NXC
Class: II
Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description: The FACE4D aligners are a series of prescription-only clear plastic removable aligners intended to incrementally move a patient's teeth from an initial position to a different end position using a software generated sequence of intermediate states. FACE4D sequentially reposition teeth by way of continuous gentle force.

When attachments are prescribed as part of the treatment plan, a disposable template is provided to assist the dental practitioner in positioning and forming the attachments from dental composite (sold separately). Attachment templates are disposable polyethylene (K200125) appliances which match the patient's existing dentition and include wells for the placement of dental composite. During the first visit, the dental practitioner uses the template in bonding dental composite to the tooth surface to create attachments on the teeth. These attachments help create forces on the tooth which can assist in aligner retention or optimized aligner force system for tooth movement.

Indications for Use: FACE4D aligners are indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars).

Method of Use:

Each aligner is worn by the patient for 20-22 hours a day and are to be removed for eating and cleaning. Aligners are replaced by the next aligner in sequence after a wear time of 1-2 weeks.

Mode of Action:

The mode of action is the same as the predicate devices and reference devices. Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement.

Testing Summary: The material used for the FACE4D is the same thermoplastic polyurethane-polyester as that cleared in K220726 K Clear Align. A biocompatibility assessment is included. Avinent conducted manufacturing validation with Vision by SoftSmile (K212770) being used to fabricate the aligners and based upon the predetermined treatment plan submitted by a dentist.

Predicate Device: K220726 K Clear Align from K Line

Reference Devices: K220287 Invisalign use with attachments K212770 Vision from SoftSmile

Substantial Equivalence:

Device	FACE4D	K Clear K220726	Invisalign K220287
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470
Device Classification Name/Device Common Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC	NXC
Classification	II	II	II
Indications for use	Face4D aligners are indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion in patients	K Clear aligners are indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion in patients with permanent	The Invisalign System is intended for the orthodontic treatment of malocclusion.

	with permanent dentition (i.e., all second molars).	dentition (i.e., all second molars).	
Intended population	Individuals with permanent dentition (all second molars).	Individuals with permanent dentition (all second molars).	Individuals with permanent dentition (all second molars).
Method of Use	Each aligner is worn by the patient for 20-22 hours a day and are to be removed for eating and cleaning. Aligners are replaced by the next aligner in sequence after a wear time of 1-2 weeks.	Each aligner is worn by the patient for 20-22 hours a day and are to be removed for eating and cleaning. Aligners are replaced by the next aligner in sequence as directed by the dental health professional.	Each aligner is worn by the patient for 20-22 hours a day and are to be removed for eating and cleaning. Aligners are replaced by the next aligner in sequence after a wear time of 1-2 weeks.
Mode of action	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement.	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement.	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement.
Material	Thermoplastic polyurethane-polyester	Thermoplastic polyurethane-polyester composite resin	Thermoplastic polymer

	composite resin		
Appliance Application	Patient removable	Patient removable	Patient removable
Attachments made from dental composite can be used	Yes		Yes
Biocompatible	Yes	Yes	Yes
OTC or Rx	Rx	Rx	Rx
Sterile	Non-sterile	Non-sterile	Non-sterile

Conclusion: Based on method of use, mechanism of action, indications for use, material and the results of non-clinical performance testing, FACE4D are substantially equivalent to K Clear K220726 from K Line. Use of attachments made from dental composite is the same for FACE4D and K220287 Invisalign from Align Technologies.

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