



February 3, 2026

Dror Orthodesign Ltd.  
Orly Maor  
Regulatory Specialist  
3 Shatner St.  
Jerusalem, 9546103  
ISRAEL

Re: K253282  
Trade/Device Name: ZSmile System  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: Class II  
Product Code: NXC  
Dated: September 28, 2025  
Received: September 29, 2025

Dear Orly Maor:

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](mailto: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.

K253282

?

Please provide the device trade name(s).

?

ZSmile System

Please provide your Indications for Use below.

?

The ZSmile System is indicated for use in movement and alignment of teeth during orthodontic treatment of malocclusion.

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

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

?

**510(k) Summary**  
**ZSmile System**  
**K253282**

**Date Prepared: January 28, 2026**

**I. SUBMITTER**

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**II. DEVICE**

Name of Device: ZSmile System  
Common or Usual Name: ZSmile System  
Classification Name: Orthodontic plastic bracket  
Regulatory Class: Class II, per 21 CFR 872.5470  
Product Code: NXC.  
Classification Panel: Dental

**III. PREDICATE DEVICE**

Name of Device: ZSmile System (former Aerodentis System) cleared under K192069  
Common or Usual Name: ZSmile System  
Classification Name: Orthodontic plastic bracket  
Regulatory Class: Class II, per 21 CFR 872.5470  
Product Code: NXC.  
Classification Panel: Dental

**IV. DEVICE DESCRIPTION**

The ZSmile System is an orthodontic system intended to adjust the patient's teeth through movement from their initial position to the desired position as a result of pulsatile mechanical force.

The device is designed to achieve orthodontic tooth movement over a period of approximately 10 hours per day (typically at night). The device is suitable for patients with full complement of permanent teeth in need of upper, lower or combined jaw treatments.

The modifications from the cleared system include:

**Adding mobile application and cloud:**

The mobile application is intended to provide the device pairing information with the ZSmile cloud

for it to be able to communicate with the patient’s smartphone via patient’s local Wi-Fi. The ZSmile Cloud is hosted on AWS supports ZSmile device registration using unique hardware identifiers and securely stores Wi-Fi credentials to enable reliable connectivity. The cloud contains non-medical functions such as a database for storing session data, logs, and device usage information.

**Additional charging option:**

Addition of option for charging by Qi-compatible wireless charging pad (not supplied).

**Pump redesign:**

The ZSmile device uses an electronic piston pump whereas the predicate Aerodentis System incorporated an electronic diaphragm pump as the internal pressure-generation element.

Both pump types operate as electrically driven, self-contained air compression modules intended to supply pulsatile pneumatic pressure to the mouthpiece. The redesign was made to reduce the overall size of the PTC unit and to lower pump operation noise levels.

**V. INDICATIONS FOR USE**

The ZSmile System is indicated for use in movement and alignment of teeth during orthodontic treatment of malocclusion.

**VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

	<b>Dror Orthodesign ZSmile System (subject device)</b>	<b>Dror Orthodesign Aerodentis System (predicate device)</b>	<b>SE determination</b>
<b>510(k) Number</b>	K253282	K192069	N/A
<b>Regulation</b>	21 CFR 872.5470	21 CFR 872.5470	SE
<b>Product Code</b>	NXC	NXC	SE
<b>Indications for Use</b>	The ZSmile System is indicated for use in movement and alignment of teeth during orthodontic treatment of malocclusion.	The Aerodentis System is indicated for use in movement and alignment of teeth during orthodontic treatment of malocclusion.	SE
<b>User Population</b>	The ZSmile System is suitable for adolescents and adults.	The Aerodentis System is suitable for adolescents and adults.	SE
<b>Components</b>	Mouthpiece and Personalized Treatment Controller Software application	Mouthpiece and Personalized Treatment Controller	Similar The addition of the software application does not change the fundamental operation of the device.

	<b>Dror Orthodesign ZSmile System (subject device)</b>	<b>Dror Orthodesign Aerodentis System (predicate device)</b>	<b>SE determination</b>
<b>Principles of Operation</b>	Inflation of the balloon within the mouthpiece provides pressure to the occluded teeth to move them into the desired position over time.	Inflation of the balloon within the mouthpiece provides pressure to the occluded teeth to move them into the desired position over time.	SE
<b>Pressure Application</b>	Pulsatile	Pulsatile	SE
<b>Daily Treatment Length</b>	10 hr/day recommended	10 hr/day recommended	SE
<b>Software</b>	Yes; used to develop a patient specific plan and control treatment delivery. Software is used in the mobile App.	Yes, used to develop a patient specific plan and control treatment delivery.	Similar The addition of the software mobile app is intended to provide the Personal Treatment Controller (PTC) pairing information with the cloud for ID registration. No safety issues.

## **PERFORMANCE DATA**

The following performance data were conducted. The ZSmile System met the predetermined acceptance criteria as established in the predicate device, ensuring substantial equivalence to the predicate. No new safety or effectiveness issues were raised during testing:

### **Software Validation**

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions”. Cybersecurity was also evaluated.

### **Electrical Safety and EMC**

Electrical Safety per IEC 60601-1 and Electromagnetic compatibility (EMC) per IEC 60601-1-2 were conducted on the ZSmile System. In addition, testing was done per IEC 60601-1-11 for home use.

Wireless communication testing was done per EN 301 489 and EN 303 417.

## **VII. CONCLUSIONS**

Dror Orthodesign Ltd. has demonstrated that the modified ZSmile System is substantially equivalent in fundamental design, technology, function, device materials, packaging, operating principal, and intended use/ indication for use to the predicate device, the cleared ZSmile System

(formerly known as Aerodentis System). The minor differences do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified ZSmile is substantially equivalent to the predicate.