September 28, 2020

Eon Dental Jordan LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K202685
Trade/Device Name: Eon Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 14, 2020
Received: September 15, 2020

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 (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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202685

Device Name
Eon Dental Aligner

Indications for Use *(Describe)*
Eon Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). Eon Aligner System positions teeth by way of continuous gentle force.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K202685
510k Summary

510k Owner	Eon Dental Jordan LLC
510k Owner Address:	385 King Abdullah II Street. Amman 11810 Jordan
Contact:	Fadi Samawi / Director of Manufacturing
Phone:	+(962)780606066
Email:	f.samawi@eonaligner.com
Submission Correspondent:	Shree Koushik Ph.D. RAC BDRA Consulting LLC 1 Clearwater Court, Damascus, MD 20872
Phone	301-922-7231
Email	bdraconsulting@gmail.com
Date Prepared:	September 11, 2020
Device Trade Name:	Eon Aligner
Classification Name	Orthodontic Plastic Bracket
Common Name:	Sequential Aligner
Classification Number	21 CFR 872.5470
Product Code	NXC
Classification	2
Predicate Device	K182826, Ormco Spark Aligner System Clearance Date: 10/11/2018

Intended Use / Indications for Use:

Eon Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). Eon Aligner System positions teeth by way of continuous gentle force

Device Description:
The Eon Aligners is a custom clear aligner system. They are a series of doctor-approved clear plastic removable aligners that are used as alternative traditional orthodontic wires and brackets for the alignment of maloccluded or misaligned teeth. This series of aligner moves the teeth gently, and in small increments, from their original misalignment to their final treated position for improved dental alignment.

An orthodontist prescribes Eon Aligners based on an assessment of the patient's teeth using a 3D intraoral scan of the patient's teeth or a physical impression. The 3D intraoral scan or physical impression are then sent to Eon Dental. The impressions are scanned using standard validated software. Using dental software intended for tooth alignment, Eon Dental designs a series of plastic trays intended to progressively realign the patient's teeth which conforms with the orthodontist's prescription. The prescribing physician reviews and approves the treatment setup before the plastic trays are produced. The treatment set up which includes a video animation of how the teeth will move during the aligner treatment and the final alignment results. Once approved, Eon Dental produces a series of dental models that correspond to the treatment stages using additive manufacturing techniques. The 3D printed models are used to manufacture the aligners using standard technique. The aligner trays for each treatment stage is thermoformed using clear thermoplastic polyurethane-polyester composite resin material. The scanning design software, 3D-Printing and aligner manufacturing was validated, and the study concluded that Eon can manufacture the aligners as intended.

Operating Principle:
Each progressive aligner is intended to be worn for 2 weeks, where gentle force is applied (by the aligner) to achieve progressive realignment of the teeth till the teeth are aligned as per treatment plan. Similar to predicates and traditional braces the treatment plan proceeds over time under clinician supervision.

Biocompatibility testing
The biocompatibility evaluation and the determination that Eon Aligners and the predicate devices are made from identical the material components, using similar manufacturing processes, and are used in the identical clinical manner, including the intended anatomical location and the frequency and duration of exposure, Eon concludes that Eon Aligners are biocompatible for their intended use.
The following biocompatibility assessments were performed by thermoplastic polymers manufacturer were included in the submission.

	Biological endpoint	**Supporting data from literature**	**Test Article**	**Rationale for why additional information is not required**
1	Cytotoxicity – MEM Elution (ISO 10993-5)	na	Thermoformed Sheet	The thermoformed sheet shows no cytotoxicity
2	Cytotoxicity study per ISO 10993-5:2009	na	Aligner material	Aligner material does not show any cytotoxicity
3	Maximization Test for delayed-type hypersensitivity (ISO 10993-10)	na	Thermoformed Sheet	The thermoformed sheet does not demonstrate any hypersensitivity

	Biological endpoint	Supporting data from literature	Test Article	Rationale for why additional information is not required
4	Intracutaneous Reactivity Test (ISO 10993-10)	na	Thermoformed Sheet	The thermoformed sheet does not demonstrate any intracutaneous reactivity
5	Oral Mucosal Irritation Test (ISO 10993-10)	na	Thermoformed sheet	The thermoformed sheet does not demonstrate any oral mucosal irritation
6	Bacterial reverse mutation assay (Ames test) per ISO 10993-3:2014	na	Aligner material	Aligner material does not demonstrate any genotoxicity, test article did not induce mutations in bacterial reverse mutation study
7	In vitro mammalian cell TK gene mutation test per ISO 10993-3:2014	na	Aligner material	Aligner material does not demonstrate any genotoxicity, chromosomal aberrations in an *in vitro* mammalian cell TK gene mutation study
8	Skin irritation study in the Japanese white rabbit per ISO 10993-10:2010	na	Aligner material	Aligner material does not demonstrate any skin irritation
9	Skin sensitization test per ISO 10993-10:2010	na	Aligner material	Aligner material does not demonstrate skin sensitization
10	Tests for systemic toxicity/Subchronic systemic toxicity test (oral route) per ISO 10993-11:2017	na	Aligner material	Aligner material does not demonstrate any sub chronic clinical toxicity
11	In vitro mammalian chromosome aberration test	NA	Aligner material	Aligner material does not demonstrate chromosomal abberrations.

Status: All tests passed. Since all tests passed, Eon

Animal or Human testing

Eon Aligners are composed of identical material components as the predicate devices, using similar manufacturing processes. They have the same intended use, including the same

intended anatomical location and frequency and duration of use. Therefore, animal and human testing was not determined to be necessary.

Non-Clinical Testing
Nonclinical testing performed evaluating multiple typical malocclusions that can be corrected by Eon Aligner. The manufacturing workflow, treatment design, additive manufacturing of tooth model and design software was performed.

Eon conducted a manufacturing fit validation study in two parts. The first part they established the for the steps involved in the process for aligners made from manual impressions and digital scans. In the second part Eon recreated 3D printed models and aligners from eight patients that had successfully undergone malocclusion treatment. The results demonstrated that the Eon Aligner can be manufactured with minimal differences between the digital inputs and final aligners demonstrating the manufacturing workflow has been validated and demonstrates that Eon can manufacture products to support intended use of the device.

Substantial Equivalence:

Eon Aligners have an identical intended use compared to the Predicate, identical materials, has identical operating principles, and uses similar manufacturing processes, Eon Dental concludes that their aligners are substantially equivalent to the predicate device.

Substantial Equivalence Table:

Manufacturer:	**Eon Aligners**	**Ormco Spark Aligner System**	**Comparison**
510k Number	NA	K182826	
Common Name	Sequential Aligners	Sequential Aligners	Same
Classification Number	872.5470	872.5470	Same
Product Code	NXC	NXC	Same
Intended Use	Eon Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). Eon Aligner System positions teeth by	Ormco Spark Aligner System are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). Ormco	Same

	way of continuous gentle force.	Spark Aligner System positions teeth by way of continuous gentle force.	
Mechanism of Action	Orthodontic movement occurs by means of gentle forces which are applied on the teeth by the aligner which follows the programmed movement approved by the dental health professional.	Orthodontic movement occurs by means of gentle forces which are applied on the teeth by the aligner which follows the programmed movement approved by the dental health professional.	Same
Manufacturer:	**Eon Aligners**	**Ormco Spark Aligner System**	**Comparison**
Patient Population	Patients with all permanent dentition	Patients with permanent dentition	Same
Material(s) Used	polyurethane-polyester copolymer resin	polyurethane-polyester copolymer resin	Same
Supplied Sterile:	No	No	Same
Worn at Night:	Yes	Yes	Yes
Dental Health Professional Review	A dental health professional takes the patient impressions/scans and sends them to the dental lab, reviews the treatment set up before the manufacturing begins. The dental health professional can reject or modify the treatment set up prior to approving it to begin fabrication. The final, fabricated aligners are sent back to the Dentist/Orthodontist who dispenses them to the patients in small sequential	A dental health professional reviews the treatment set up before the manufacturing begins. The dental health professional can reject or modify the treatment set up prior to approving it to begin fabrication.	Same

	stages and monitors the patient's orthodontic tooth movement until the end of patient aligner treatment'.		

Conclusion

Since Eon Aligners have an identical intended use compared to the Predicate, identical materials, has identical operating principles, and uses similar manufacturing processes, Eon Dental concludes that their aligners are substantially equivalent to the predicate device.