March 16, 2022

K Line Europe GmbH
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K220726
Trade/Device Name: K Clear
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: March 11, 2022
Received: March 14, 2022

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,

Michael E. Adjodha, M.ChE.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K 220726

Device Name
K Clear

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

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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K220726

510(k) Summary
K Line Europe, GmbH
K Clear
2/2/2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	K Line Europe, GmbH Niederrheinstraße 16 40474 Dusseldorf, Germany
Telephone:	+49 211 93896976
Official Contact:	Sherif Kandil, CEO
Email:	sherif@clearxaligners.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	K Clear
Common Name:	Aligners, sequential
Classification Name:	Orthodontic Plastic Bracket
Classification Regulations:	21 CFR 872.5470
Device Class:	Class II
Product Code:	NXC
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and design principles to the following predicate and reference devices:

510(k)	Predicate Device Name	Company Name
K212660	Smylio Invisible Clear Aligners	Smylio, Inc

DEVICE DESCRIPTION

The K Line K Clear 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. K Clear sequentially reposition teeth by way of continuous gentle force.

The technology and overall process is identical to that used by the Predicate device, Smylio Invisible Clear Aligners (K212660) and other sequential aligner systems currently being legally marketed.

INDICATIONS FOR USE/INTENDED USE

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

EQUIVALENCE TO MARKETED DEVICE

Overall, the Subject device is substantially equivalent to the Predicate device with respect to Indications for Use and technological principles. The Comparison table below compares parameters and characteristics of the Subject device and Predicate/reference devices.

Predicate Device Comparison Table

Parameter	**Subject Device** K Clear K Line Europe, GmbH	**Predicate Device** Smylio Invisible Clear Aligners Smylio, Inc K212660	**Comparison**
Regulation #	21 CFR 872.5470	21 CFR 872.5470	***Same***
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	***Same***
Product Code	NXC	NXC	***Same***
Classification	Class II	Class II	***Same***
Indications for Use/Intended Use	K Clear aligners are indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars).	The Smylio Invisible Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion.	***Highly Similar***
Intended Population	Individuals with permanent dentition (all second molars).	Not specified.	***Similar***
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.	***Same***
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 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 as directed by the dental health professional.	***Same***
Material	Thermoplastic polyurethane-polyester composite resin	Thermoplastic polyurethane-polyester composite resin	***Same***
Appliance Application	Patient removable	Patient removable	***Same***
Design			***Same***
Biocompatible	Yes	Yes	***Same***
OTC or Rx	Rx	Rx	***Same***
Sterile	Non-sterile	Non-sterile	***Same***

The wording of the Indications for Use of the Subject device is highly similar to that of the Predicate device, differing slightly in wording and device name. The Predicate device Indications for Use statement does not include a limitation on patient population and is inclusive of the intended population of the Subject device. The intended use of both devices to treat tooth malocclusion is the same for the Subject and Predicate devices.

TECHNOLOGICAL CHARACTERISTICS

Orthodontic tooth movement occurs through forces applied to the teeth by the appliance as each tooth follows the predetermined displacement based on a dental health professional's prescription. The Subject device mode of action, method of use and sterilization status are the same as the Predicate device.

The Subject and Predicate devices are both fabricated of non-sterile, biocompatible thermoplastic polyurethane-polyester composite resin material. The Subject device mode of action and method of use are the same as the Predicate device and supports a determination of substantial equivalence.

PERFORMANCE DATA

Due to the difficulty in evaluating this type of dental device in a laboratory environment, no direct performance bench testing of the aligners was performed. The use of thermoplastic materials for sequential aligners intended to treat malocclusions have been well documented in scientific literature regarding incremental tooth moving forces.

A manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing process for K Clear aligners. A qualitative validation was performed to demonstrate the device is manufactured and performs as intended. A shelf-life/aging study was performed to support device labeling.

Biocompatibility evaluation and testing for the aligner material was conducted in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

The following biological tests were performed:

Biological Endpoint	**Relevant Standard**
Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2010
Irritation	ISO 10993-10:2010
Sub-chronic toxicity	ISO 10993-11:2017
Genotoxicity	ISO 10993-3:2014

The performance of sequential aligners in the clinical environment has been well established since the first such devices were cleared by the FDA in 1998 under product code NXC. No clinical or animal testing data is included in this submission.

CONCLUSION

Overall, the Indications for Use statement for the Subject and Predicate devices is highly similar.

Overall, the Technological Characteristics, Materials, Prescription Use and Non-sterile status of the Subject device are the same or highly similar to the Predicate device. The use of Software to produce the Subject and Predicate devices is the same. Minor differences between the Subject and Predicate devices were mitigated through performance testing of the Subject device.

Overall, the K Line K Clear aligners are substantially equivalent to the Predicate device.