May 22, 2023

3M Company, Unitek Orthodontic Products
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K231464
Trade/Device Name: 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 19, 2023
Received: May 19, 2023

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 -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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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.

Submission Number *(if known)*

K231464

Device Name

3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)

Indications for Use *(Describe)*

3M Clarity™ Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.

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.

510(k) Summary
3M™ Clarity™ Aligners
(Flex and Force)

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information

510(k) Submitter……...3M Company
Unitek Orthodontic Products
2510 Conway Avenue
St. Paul, MN 55144
Establishment Registration No.: 2110898

Primary Contact…… Brittany Randolph
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Subject Device Information

Submission Date……09 May 2023

Proprietary Trade Name…….3M™ Clarity™ Aligners

Device Name…….……...….Aligner

Common Name…….Sequential Aligner

Classification Name…… Orthodontic Plastic Bracket

Regulation Number……..21 CFR 872.5470

Product Code…….....…….NXC

Classification Panel……..…Dental Products Panel 76

Classification…….Medical Device, Class II

Indications for Use:

3M™ Clarity™ Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Predicate Device:

Product Name	**3M Clarity Aligners (3M Clarity Aligners-Force, 3M Clarity Aligners-Flex)**
Manufacturer	3M Company Unitek Orthodontic Products 2510 Conway Avenue St. Paul, MN 55144
510(k) Number	K211190
Device Class	2

Description of Device:

3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) are a series of clear plastic aligners that offer a solution for patients who want an aesthetic orthodontic treatment by utilizing a set of removable aligners to correct tooth malocclusions without the use of conventional wire and bracket orthodontic technology. The present Premarket Submission is for the simplification in the number of formulations of the aligner material. This simplification allows for streamlined manufacturing processes so that both 3M Clarity Aligners-Flex and 3M Clarity Aligners-Force can be composed of the same material with differing flexibilities. The aligners will still be named 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex).

3M is offering a treatment plan with two different aligner flexibilities where the dental health professional will determine which degree of flexibility to use during the treatment plan. 3M Clarity Aligners-Flex is designed to be more flexible thereby increasing patient comfort and ease of insertion and removal. 3M Clarity Aligners-Force is designed to be more rigid increasing the force persistence. 3M will continue to offer the option of combination treatment plans where both 3M Clarity Aligners-Flex and 3M Clarity Aligners-Force can be used.

A dental health professional (e.g., orthodontist or dentist), prescribes 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) based on an assessment of the patient's teeth and determines a course of treatment with the system. Patient data is collected via intra-oral scanning or taking physical impressions. The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, 3M produces trays, which are formed of clear, thin, thermoformed plastic. The trays are sent back to the dental health care professional who then provides them to the patient, confirming fit and design. The dental care professional monitors treatment from the moment the first aligner is delivered to

when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at any time.

Technological Characteristics:

3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) and the previously cleared aligners, 3M Clarity Aligners (3M Clarity Aligners-Force, 3M Clarity Aligners-Flex) (**K211190**) technological characteristics are similar but not identical. They have the same design, device features, software, and manufacturing processes but the material is different. The subject device introduces a new material formulation but the simplification of the aligner material formulation does not impact the safety and effectiveness. Differences in technological characteristics of the subject device and the predicate device have been evaluated in accordance with the Agency's Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] dated July 28, 2014. Differences in the technological characteristics do not raise significant concerns about safety or effectiveness.

Substantial Equivalence – Intended/Indicated Use, Technological Characteristics		
Feature	**Predicate Device:** 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)	**Subject Device:** 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)
Manufacturer	3M Company Unitek Orthodontic Products 2510 Conway Avenue St. Paul, MN 55144	No change
510(k) Number	K211190	To be determined
Regulation Number	21 CFR 872.5470	No change
Product Code	NXC	No change
Device Class	Class II	No change
Intended Use:	This product is intended for use in orthodontic treatment.	No change
Indications for Use:	3M Clarity Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.	No change
Manufacturing Process	Aligners are manufactured using a thermoform process.	No change

Substantial Equivalence – Intended/Indicated Use, Technological Characteristics		
Feature	**Predicate Device:** 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)	**Subject Device:** 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)
Material	Two Copolyesters	Copolyester Poly Cyclohexylenedimethylene Terephthalate Glycol-Modified (PCTG)
Technical Features and Properties	Orthodontic tooth movements occur through forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	No change
Software	Proprietary software is used in the manufacturing process of the currently commercialized aligners.	No change

Performance Testing:

Results of translucency properties, abrasion resistance, formability, mechanical stability, dimensional stability, force persistence, fatigue cracking resistance, chemical staining resistance, transportation, and use life testing among others are included in this Premarket submission. All performance testing shows acceptable results for all tested samples.

Software

There are no significant changes in the software used to prepare treatment plans or produce trays compared to the predicate device, 3M Clarity Aligners (3M Clarity Aligners-Force, 3M Clarity Aligners-Flex).

Biocompatibility Testing

3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) were assessed as a mucosal membrane contacting device that is intended to be in contact with the body for greater than 30 days.

In accordance with the combined guidance found in ISO 10993, ISO 7405, Testing guidelines outlined in the US FDA Docket Number FDA-2013-D-0350, and Japan: PSEHB/MDED No. 0106-1 and 0612-4, the following endpoints below must be considered in the biocompatibility evaluation of this product: Physical and/or Chemical Information, Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Sub-acute Toxicity, Sub-chronic Toxicity, Genotoxicity, Implantation, and Chronic Toxicity.

A Diplomate of the American Board of Toxicology has assessed the safety of this product and has determined that it is safe for its intended use.

Substantial Equivalence

Substantial equivalency of the subject device, 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) to the predicate device, 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) is made on the basis of intended/indicated use, technological characteristics, and performance testing. The subject device and the predicate device are similar in that they have:

- same intended use,
- same indications for use,
- same design and device features
- same manufacturing software
- same manufacturing processes
- similar technological characteristics

The differences in the technological characteristics between the subject device and predicate device do not raise different questions of safety or efficacy. Therefore, the subject device is found to be substantially equivalent to the legally marketed predicate device, 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) **(K211190).**

Conclusion:

The indications for use of 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) are the same as the previously cleared device, 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) **(K211190).** Both devices are orthodontic clear tray aligners with a multi-layer film construction. The subject devices technological characteristics are similar but not identical to the predicate device.

Differences in technological characteristics of the subject device and the predicate device has been evaluated in accordance with the Agency's Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] dated July 28, 2014. Differences in the technological characteristics do not raise significant concerns about safety or effectiveness. Bench testing was conducted to compare the performance of 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) to the previously cleared device, 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex) **(K211190).** Testing demonstrates that the safety and performance of the subject device are substantially equivalent to the predicate device.