September 29, 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: K233257
Trade/Device Name: 3M™ Clarity™Aligners with Quick Attachments
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 28, 2023
Received: September 28, 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, 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

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)*

KXXXX K233257

Device Name

3M™ Clarity™ Aligners with Quick Attachments

Indications for Use *(Describe)*

3M™ Clarity™ Aligners with Quick Attachments 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.

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

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510(k) #: KXXXX K233257

510(k) Summary

Prepared on: 2023-09-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	3M Company, Unitek Orthodontic Products
Applicant Address	2510 Conway Avenue St.Paul MN 55144 United States
Applicant Contact Telephone	612-710-9847
Applicant Contact	Mrs. Hillary Peetsch
Applicant Contact Email	hpeetsch@mmm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	3M™ Clarity™ Aligners with Quick Attachments
Common Name	Orthodontic plastic bracket
Classification Name	Aligner, Sequential
Regulation Number	872.5470
Product Code	NXC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231464	3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex	NXC

Device Description Summary

21 CFR 807.92(a)(4)

3M™ Clarity™ Aligners with Quick Attachments, is a clear plastic sequential aligner 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. 3M™ Clarity™ Aligners with Quick Attachments utilize the option of pre-formed and pre-cured attachments offering a more accurately shaped and precisely placed attachment. Attachments help create forces on the tooth which can assist aligner retention or optimized aligner force system for tooth movement. 3M Clarity Aligners with Quick Attachments provide the option to form the attachments via an empty attachment template that is filled with adhesive and cured on the teeth or by pre-formed 3D printed custom attachments. The aligners, with or without attachments, are for orthodontic treatment of malocclusions.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both predicate and subject device have the same indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

3M™ Clarity™ Aligners with Quick Attachments are substantially equivalent to the predicate device. 3M™ Clarity™ Aligners with Quick Attachments are comparable to previously cleared device, 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-

Flex) (K231464) as they have the same indications for use, same manufacturing processes, same design, same device features, software, and are considered substantially equivalent (21 CFR 807.100).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The proposed Quick Attachment alternative attachment delivery mechanism completed functional and performance testing; such tests include but are not limited to: abrasion, bond strength, flexural strength, and stain resistance.

Not applicable

The performance testing showed the alternate Quick Attachment delivery mechanism does not impact the safety and effectiveness profile of the 3M™ Clarity™ Aligners-Force, 3M™ Clarity™Aligners-Flex and is substantially equivalent to the predicate device.