3M Company
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

November 26, 2018

Re: K183159
Trade/Device Name: 3M Clarity Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 13, 2018
Received: November 15, 2018

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.26 13:11:50 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

3M™ Clarity™ Aligners

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 08/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

3M™ Clarity™ Aligners

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.

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

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Section 3

510(k) Summary

3M™ Clarity™ Aligners

510(k) Summary

510(k) Summary

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

510(k) Submitter…… 3M Company, 3M Health Care
2510 Conway Avenue
St. Paul, MN 55144
Owner/Operator No.: 2110898
Establishment Registration No.: 2110898

Primary Contact……Yanine Garcia-Quezada
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mcburville@mmm.com

Submission Date……08 November 2018

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 Devices:

Invisalign® System (K081960) [Primary Predicate]

3M Clear Tray Aligner (K163689) [Predicate Device]

Description of Device:

The 3M Clarity Aligners 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.

3M Company, 3M Health Care is submitting this 510(k) Premarket Notification because the Indications for Use are changing with the removal of the treatment limitation of patients with permanent dentition (i.e., all second molars). The updated indications for use are the same as the primary predicate Invisalign. Both devices are indicated for the correction of malocclusions. Neither of the indications specify the types of tooth movement to be used.

The change in indications for use to remove specific tooth movement types for the 3M Clarity Aligners does not affect the design, material composition, manufacturing processes and related software, these remain the same as the cleared 3M Clear Tray Aligner (K163689). There are no changes to the current contraindications. There is the addition of a precaution addressing the need to wear gloves when handling adhesives, and the expansion of one note where examples have been added as the original note did not include examples of supplemental treatments. Warning and precautions associated with the use of attachments, and one warning associated with the use of aligner tools to seat and/or remove aligners were also added.

Technological Characteristics:

The material composition of the 3M Clarity Aligners is different from the material composition of the primary predicate Invisalign System. However, the material composition remains identical to the previously cleared 3M Clear Tray Aligner (K163689). The 3M Clarity Aligners and the previously cleared 3M Clear Tray Aligner have the same technological characteristics, such as design, material composition, device features, as well as their manufacturing processes.

Software

There are no changes in the software compared to the existing 3M Clarity Aligners. The software design and development, software development methodology, software development process and environment are identical for the existing predicate device and the modified 3M Clarity Aligners.

Testing

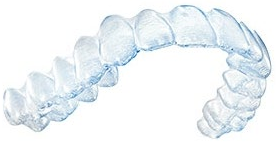
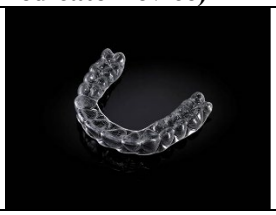
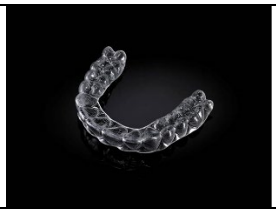
No additional testing has been included on this submission. Biocompatibility tests, performance testing and software verification and validation testing data was previously submitted and reviewed to support clearance of the predicate device 3M Clear Tray Aligner under premarket notification K163689.

Substantial Equivalence Comparison

The following table compares the 3M Clarity Aligners to the primary predicate device Invisalign System, and to the predicate device 3M Clear Tray Aligner with respect to intended use, technological characteristics and principles of operation.

Table #1

Feature	Invisalign® System (Primary Predicate)	3M™ Clear Tray Aligner (Predicate Device)	3M™ Clarity™ Aligners
510(k) Number	K081960	K163689	To be determined
Manufacturer	Align Technology, Inc.	3M Company, 3M Unitek	3M Company, 3M Health Care
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC	NXC
Device Class	Class II	Class II	Class II
Indications for Use	The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The 3M Clear Tray Aligner system is a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force.	3M Clarity Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.
Mode of Action	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
Material	Thermoplastic	Thermoplastic	Thermoplastic
Software Used for Ordering Workflow	Yes	Yes	Yes

Feature	Invisalign® System (Primary Predicate)	3M™ Clear Tray Aligner (Predicate Device)	3M™ Clarity™ Aligners
Design			

Substantial Equivalence Conclusion:

3M Clarity Aligners are substantially equivalent to the predicate device Invisalign cleared under K081960 in that both systems have the same indications for use. This premarket notification is being submitted to expand the indications for use and to update labeling. There are no changes in the technological characteristics, design, material composition, device features to the previously cleared 3M Clear Tray Aligner (K163689).