September 5, 2019

3M Company
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K192119
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: August 5, 2019
Received: August 6, 2019

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 Michael Adjodha
Acting Assistant 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)*

K192119

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.

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510(k) Summary

K192119

510(k) Summary

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

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

Primary Contact……Yanine Garcia-Quezada
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Submission Date……24 May 2019

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:

3M Clarity Aligners (K183159) [Primary 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.

A dental health professional (e.g. orthodontist or dentist), using a standard personal computer prescribes 3M Clarity Aligners based on an assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth and completes a prescription form using a standard dental software used for tooth alignment, 3M then designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription using a standard dental software used for tooth alignment. 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. Over a period, additional trays are provided sequentially to the patient by the dental health professional to gradually move the target teeth to the designed position. 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.

There are no changes being made to the 3M Clarity Aligners themselves. Both the proposed 3M Clarity Aligners and the primary predicate 3M Clarity Aligners (K183159) have the same

indications for use. The present premarket submission is to account for the overall software cumulative changes including the integration of the ULab software (K171295).

Technological Characteristics:

The modified 3M Clarity Aligners and the previously cleared 3M Clarity Aligners (K183159) have the same technological characteristics, such as design, material composition, device features, as well as their manufacturing processes.

Performance Testing:

Results of verification and validation testing demonstrate the proposed 3M Clarity Aligners showed conformity with pre-established specifications and acceptance criteria. Software testing was conducted in accordance with "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" dated January 11, 2002 and Medical Device Software – Software Life Cycle Processes; ANSI/AAMI/IEC 62304:2015.

Substantial Equivalence Comparison

	Primary Predicate Device: 3M™ Clarity™ Aligners (K183159)	**Proposed Device: 3M™ Clarity™ Aligners**	**Comparison:**
Indications for Use	3M Clarity Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion	3M Clarity Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion	Identical
Software Description	The Oral Care Portal implements 3M Clarity Aligners ordering and review/approval process. Doctors may submit orders through the Order Wizard. The model is then manipulated outside of the system for the final occlusion based on the characteristics in the submitted order. This setup model is sent back to the system for the doctor to review, and subsequently approved or rejected. If the doctor rejects the model, the process is repeated until the doctor approves the model.	The Oral Care Portal implements 3M Clarity Aligners ordering and review/approval process. Doctors may submit orders through the Order Wizard. The model is then manipulated outside of the system for the final occlusion based on the characteristics in the submitted order. This setup model is sent back to the system for the doctor to review, and subsequently approved or rejected. If the doctor rejects the model, the process is repeated until the doctor approves the model.	Identical
Mode of Operation	Oral Care Portal software performs the following operations: -Produce 3D model file of a digital scan or from a PVS impression model -Identifies individual teeth that will require treatment -Creates a treatment plan -Communicates with Dental Health Professional where treatment plan is reviewed, if modifications are requested these are applied prior to approval.	Oral Care Portal software performs the following operations: -Produce 3D model file of a digital scan or from a PVS impression model -Identifies individual teeth that will require treatment -Creates a treatment plan -Communicates with Dental Health Professional where treatment plan is reviewed, if modifications are requested these are applied prior to approval.	Identical
Software Elements	An electronic description form and process used to depict, edit, view, monitor and approve an orthodontic treatment plan	An electronic description form and process used to depict, edit, view, monitor and approve an orthodontic treatment plan	Identical

Software Elements	Treatment Plan: -Dental Health Professional accesses 3M OCP web-based application -Treatment plan is created and submitted to 3M	Treatment Plan: -Dental Health Professional accesses 3M OCP web-based application -Treatment plan is created and submitted to 3M	Identical
Software Elements-ULab	Set Up Record Treatment Plan: -Dental Health Professional accesses 3M OCP web-based application and finds ULab icon -Dental Health Professional signs into ULab software -Treatment plan is created and submitted to 3M -3M creates treatment plan based on ULab setup record -3M and Dental Health Professional interact until design treatment is approved	Full Treatment Plan: -Dental Health Professional accesses 3M OCP web-based application and finds ULab icon -Dental Health Professional signs into ULab software -Treatment plan is created and submitted to 3M -3M manufactures aligners Note: there are no records QC or setup review steps in the process. The order goes directly to production software	Proposed software includes ULab treatment plan that eliminates the interaction with 3M technicians. The Dental Health Professional owns the treatment planning process and submits directly to 3M for manufacturing Note: both ULab Set Up Record and Full Treatment plans are available. The Dental Health Professional chooses which ULab plan to use

Substantial Equivalence Conclusion:

The 3M Clarity Aligners are substantially equivalent to the primary predicate device (21 CFR 807.100). The 3M Clarity Aligners are identical in all aspects to the primary predicate, other than software improvements and the integration of the ULab software. 3M Clarity Aligners are as safe, as effective, and substantially equivalent to the predicate device in terms of intended use, indications for use, design, performance, technological characteristics, mechanism of action, composition and biocompatibility.