DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 27, 2017

3M™ Unitek Corporation
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, New York 55313

Re: K163689
Trade/Device Name: 3M™ Clear Tray Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: October 7, 2016
Received: December 28, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

3M™ Clear Tray Aligner

Indications for Use *(Describe)*

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.

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

3M Unitek

510(k) Summary

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

510(k) Submitter…… 3M Unitek Corporation
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Submission Date……07 October 2016

Proprietary Trade Name……To be Determined

Device Name……..…….3M™ Clear Tray 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:

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.

Predicate Devices:

Invisalign® System (K081960) [Primary Predicate]
ClearCorrect System (K113618) [Predicate Device]

Description of Device:

The 3M Clear Tray Aligner System is 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 the 3M Clear Tray Aligner system 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.
The technology is essentially identical to that used by a number of sequential aligner systems including the predicates referenced in Table #1.

Technological Characteristics:

Treatment of tooth malocclusions via a series of plastic appliances that incrementally moves teeth to a desired end-state is the technological principle for both the subject and predicate devices. A comparison between the technological characteristics of the 3M Clear Tray Aligner and that of legally marketed predicate devices has been performed. The results of this comparison demonstrate that the design, technology, materials and composition of the 3M Clear Tray Aligner are substantially equivalent to the predicate devices.

Mechanism of Action:

The mechanism of action is similar to the predicate devices and supports a determination of substantial equivalence. Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional's prescription.

Performance Testing

Although, bench testing was not performed due to the difficulty in evaluating this type of dental device in a laboratory setting; translucency testing, shelf life and life expectancy tests were conducted on the thermoformed tray material which showed acceptable translucency properties and shelf life requirements for all tested samples.

There is sufficient information available from the scientific literature and from the predicate devices to demonstrate that sequential aligners provide reasonable assurance of safety and effectiveness.

Biocompatibility Testing

The biocompatibility evaluation for the device was conducted in accordance with the US FDA Docket Number FDA-2013-D-0350. CDRH Document Number 1811 "Use of International Standard ISO 10993-1, Biological evaluation and testing within a risk management process – Guidance for Industry and Food and Drug Administration Staff" as recognized by FDA. The aligner is considered mucosal membrane contacting for a duration of greater than 30 days. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The results of the testing met the requirements of the study protocols and the material is considered non-cytotoxic, non-sensitizing and is not an intracutaneous irritant. The results of the studies further support a determination of substantial equivalence.

Software Verification and Validation Testing

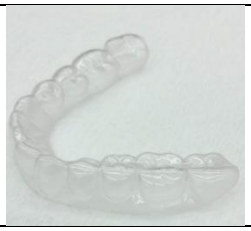
Software verification and validation testing were conducted on the software that facilitates ordering and processing of the 3M Clear Tray Aligner to support that the device is as safe and effective as the predicates. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Substantial Equivalence Comparison

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

Table #1

Feature	3M™ Clear Tray Aligner	Invisalign® System (Primary Predicate)	ClearCorrect System (Predicate Device)
510(k) Number	To be determined	K081960	K113618
Manufacturer	3M Unitek	Align Technology, Inc.	ClearCorrect LLC
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 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.	The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.
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
Material Properties	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.

Feature	3M™ Clear Tray Aligner	Invisalign® System (Primary Predicate)	ClearCorrect System (Predicate Device)
Software Used for Ordering Workflow	Yes	Yes	Yes
Design			

Substantial Equivalence Conclusion:

The Clear Tray Aligner has substantially equivalent Indications for Use as the identified predicate devices. The verbiage of the Indications of Use of the subject device is slightly different than the declared predicates; however, these slight differences do not alter the intended therapeutic use of the device as compared to the predicates.

The conclusions drawn from the data included in this submission, demonstrates that the 3M Clear Tray Aligner is as safe, as effective, and is substantially equivalent to the predicate devices in indications for use, design, technological characteristics, mechanism of action, performance, materials and biocompatibility.