December 20, 2019

DenMat Holdings, LLC
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K192470
Trade/Device Name: DenMat Orthodontic Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: December 3, 2019
Received: December 4, 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 Srinivas “Nandu” Nandkumar, Ph.D.
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)*

K192470

Device Name

DenMat Orthodontic Aligner

Indications for Use *(Describe)*

The DenMat Orthodontic Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and 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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5 510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, DenMat Holdings LLC is hereby submitting this 510(k) summary.

Submitter [510(k) owner]

DenMat Holding, LLC

1017 W. Central Avenue

Lompoc, CA 93436

Company Contact

Tom Juarez
Director RA/QA
DenMat
P: (805) 346-3780
C: (805) 345-0632
tjuarez@denmat.com

Submitted Device Information

Trade Name: DenMat Orthodontic Aligner
Common Name: Aligner, sequential
Classification Name: Orthodontic Plastic Bracket, Dental Devices

Classification Information

Classification: Class II
Classification Regulation: 21 CFR 872.5470
Classification Product Code: NXC

Legally Marketed Predicate Devices

The DenMat Orthodontic Aligner manufactured by DenMat Holdings, LC (DenMat) is substantially equivalent to the following device currently in commercial use:

- Device Trade Name: Clear Image Aligners
- Manufacturer: Specialty Appliance Works, Inc.
- Address: 4905 Hammond Industrial Drive, Cumming, GA 30041
- 510(k) number: K183643
- Product Code: NXC

Submitted Device Description

The DenMat Orthodontic Aligner consists of a series of clear plastic trays, which fit over a patient's teeth, and move the teeth by external force a small amount daily. This material is the only patient contacting material, there are no lubricants,

coatings, or colorants. The dental professional determines the ultimate movement needed, and an FDA-cleared software design tool is used to produce a treatment series of aligners to achieve this goal. The trays are produced when the software design tool outputs a file to a 3-D printer, which produces a resin model. The resin used to manufacture the model has been tested for cytotoxicity and has been shown to be non-cytotoxic. The positive mold is cleaned with isopropyl alcohol prior to vacuum forming the aligner.

The resin model is then used with the FDA-cleared plastic material to thermoform the plastic aligner. The aligners, once formed, are rinsed with distilled water only, and air dried. Depending on the prescription, 10 to 15 aligners are produced for a single patient set. Each aligner is worn for 2 weeks, and the dental professional checks progress during treatment.

Intended Use

The DenMat Orthodontic Aligner is intended to be used under the supervision of a dentist/orthodontist after a comprehensive dental exam has been completed and the patient has been cleared for orthodontic treatment. The dentist/orthodontist takes a scan/impressions that are then sent to the lab where aligners are fabricated and sent back to the dentist to confirm fit and function and then used by a patient in the home/work/leisure environment. The aligner is to be used 20-22 hours per day for 2 weeks, then be replaced by the next aligner in the series, until prescribed tooth movement is achieved.

The patient is instructed in the care of the aligner to maintain clarity of plastic and continued force on teeth and instructed to return to their dentist/orthodontist for any issues with aligner fit or pain.

Indications for Use:

The DenMat Orthodontic Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

Substantial Equivalence

The *DenMat Orthodontic Aligner* is substantially equivalent to the predicate device, in which the basic features and intended uses are essentially the same. The identical 3-D design software and plastic thermoform material are used by both manufacturers. The software and material have both been cleared by the FDA under their own 510(k)s.

The ***DenMat Orthodontic Aligner*** system is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the Clear Image Aligners, and raises no new issues of safety or

effectiveness.

COMPARISION OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The DenMat Orthodontic Aligner system is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the Clear Image Aligners, and raises no new issues of safety or effectiveness.

The similarities and differences between the predicate and proposed aligners are:

Property or Characteristic	Proposed Device DenMat Holdings, LLC DenMat Orthodontic Aligner	Predicate Device Specialty Appliance Works, Inc. Clear Image Aligners K183643	Comments
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	Same
Classification	II	II	Same
Indications for Use	The DenMat Orthodontic Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	The Clear Image Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	Same
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Same
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the orthodontist/dentist prior to using the next sequential aligner tray.	Each preformed plastic tray is worn by the patient as prescribed by the orthodontist/dentist prior to using the next sequential aligner tray.	Same
Material	Essix Ace plastic (K062828)	Essix Ace plastic (K062828)	Same
Prescription or OTC	Prescription	Prescription	Same
Software Used during manufacturing	Use of 3Shape Ortho System (K171634/K152086)	Use of 3Shape Ortho System (K171634/K152086)	Same
Provided Non-Sterile	Yes	Yes	Same

Summary of Substantial Equivalence:

Based on the information presented in this submission, DenMat Holdings, LLC concludes that the DenMat Orthodontic Aligners are substantially equivalent to the predicate device in regard to indications for use, design and technology.