DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2016

Martz, Inc.
c/o Dr. Mason Diamond
Texel Fortis, LLC
150 Levinberg Lane
Wayne, NJ 07470

Re: K151965
Trade/Device Name: Dentii System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: II
Product Code: NXC
Dated: February 8, 2016
Received: February 12, 2016

Dear Dr. Diamond:

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 yours,

for Erin I. Keith, M.S.
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)*
K151965

Device Name

Dentti System

Indications for Use *(Describe)*

"The Dentti System is 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Dentti System

Submitter:

Martz Inc.
8421 Blue Heron Drive
Bakersfield, CA 93312

Contact Person:

Mason W. Diamond, DDS
Texel Fortis, LLC
150 Levinberg Lane
Wayne, NJ 07470
Phone: 508-333-0108
Fax: 973-305-0213
masonwd@aol.com

Date Prepared:

March 10, 2016

Trade Name:

Dentti System

Classification Name:

Orthodontic Plastic Bracket (Sequential Aligner)

Regulation Number:

21 CFR 872.5470

Product Code:

NXC

Predicate Devices:

Invisalign System (Align Technologies, Inc) – K081960
Clear Image™ Aligners (Specialty Appliances Works, Inc.) – K071970
ClearCorrect System (ClearCorrect LLC) – K113618

Device Description:

The Dentti System is a series of clear plastic aligners that are used to replace traditional orthodontic wires and brackets for the alignment of maloccluded or misaligned teeth. This series of aligners moves the teeth gently, and in small increments, from their original to their final treated position for improved dental alignment.

The Dentist will provide a scan of the patient's current dentition along with instructions for the treatment plan. The dental laboratory will generate a series of 3-D computer-designs of the modified dentition that the Dentist will review. Upon approval, the models will be generated and used to fabricate the sequential aligners according to the dentist's prescription. The aligners are fabricated from commonly used thermoformed polyurethane plastic material.

The aligners are sent back to the Dentist, who then provides them to the patient, confirming the fit and design. Over a period of months, additional aligners will be provided sequentially to the patient by the Dentist to gradually move the selected teeth to the desired position. The Dentist will monitor the treatment from the moment the first aligner is delivered to when treatment is completed. The aligners are held in place by pressure and can be removed by the patient at any time. This technology is essentially identical to that used by a number of sequential alignment systems, including the predicate devices.

Indications for Use: The Dentti System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Functional Testing: No functional testing was required.

Mechanism of Action: Mild force is applied to the teeth via intentional distortion of the plastics when the aligners are seated in the mouth. Progressive changes in tooth position are introduced with each subsequent aligner. The Dentist can adjust the aligners as needed. The aligners can be removed and discontinued, if necessary

Summary of Technological Characteristics: Martz, Inc. manufactures the customized aligners based on models or scans, and a prescription sent to the company by the prescribing dentist. The models are made after the clinician has assessed the patient's teeth, designed a treatment plan, and taken the impressions.

Biocompatibility: The material used for fabrication of the Dentti System is a commonly-used thermoformed polyurethane material, used in many dental appliances, including the ClearCorrect System predicate(K113618). The thermoformed polyurethane material is commercially available in the U.S. and its biocompatibility has already been well established. The material used in the FDA-Cleared ClearCorrect System (K113618) is exactly the same as the material used in the Dentti aligners (K151967). In both cases, standard pressure/vacuum thermoforming units are used to fabricate the Dentti and ClearCorrect appliances. In both cases, the Zendura thermoformable sheet material is processed according to the manufacturer's instructions. Since the polyurethane and the process used in fabricating the Dentti aligners is the same as the predicate device, and since biocompatibility has already been established, no additional testing is required to demonstrate biocompatibility of the proposed device.

Performance Testing: No bench testing was warranted for this product because the scientific literature and similarity in design, materials and use to the predicate devices assure that the aligners are suitable for the specified intended use.

Substantial Equivalence Discussion: The design, indications for use, material composition, mechanism of action, and technological characteristics of the Dentti System, were Substantially Equivalent to those of the Invisalign, Clear Image systems, and ClearCorrect Systems (predicate devices).

Martz, Inc. has demonstrated that, based on the established evidence presented in the table below, the Dentti System is Substantially Equivalent to the Invisalign, Clear Image and ClearCorrect System predicate devices, in terms of intended use, material composition, fundamental scientific technology, principles of operation, and basic design."

Substantial Equivalence Comparison

Characteristic	Dentti System – K151965	Invisalign System – K081960	Clear Image™ Aligners – K071970	ClearCorrect System – K113618
Device Classification Name	Orthodontic Plastic Bracket (Sequential Aligners)	Orthodontic Plastic Bracket (Sequential Aligners)	Orthodontic Plastic Bracket (Sequential Aligners)	Orthodontic Plastic Bracket (Sequential Aligners)
Regulation Number	872.5470	872.5470	872.5470	872.5470
Product Code	NXC	NXC	NXC	NXC
Indications for Use	"The Dentti System is indicated for the alignment of teeth during orthodontic treatment of malocclusion."	"The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion."	"The Clear Image™ Aligners system in intended to correct minor discrepancies in the alignment of malocclusion anterior teeth on patients with permanent dentition (second molars) by moving the teeth with a progressive series of clear thin thermoformed plastic aligners, fabricated in stages to gradually align the teeth over a period of several months. The aligners are completely removable by the patient and may be discontinued at any time."	"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 force."

Characteristic	Dentti System – K151965	Invisalign System – K081960	Clear Image™ Aligners – K071970	ClearCorrect System – K113618
Mechanism of Action ,	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces.	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces.	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces.	Alignment of teeth by sequential use of preformed trays.
Software	Yes	Yes	No	Yes
Materials that Contact the Patient	Commonly used thermoformed plastic material - Thermoformed Polyurethane (Zendura)	Commonly used thermoformed plastic material	Commonly used thermoformed plastic material Thermoformed Polycarbonate	Commonly used thermoformed plastic material – Thermoformed Polyurethane (Zendura)
Aligner Design	Covers buccal, lingual and occlusal surfaces of the teeth like a custom tray. When using the modified tray design, space is left for so thin attachments could be affixed to the teeth to aid retention.	Covers buccal, lingual and occlusal surfaces of the teeth like a custom tray. In addition, attachments could be affixed to the teeth to aid retention	Covers buccal, lingual and occlusal surfaces of the teeth like a custom tray.	Covers buccal, lingual and occlusal surfaces of the teeth like a custom tray. In addition, attachments could be affixed to the teeth to aid retention.
Single Use	Yes – Multiple use by the same patient	Yes – Multiple use by the same patient	Yes – Multiple use by the same patient	Yes – Multiple use by the same patient
Supplied Sterile	No	No	No	No
Biocompatibility	Established for commonly used thermoformed plastic material	Established for commonly used thermoformed plastic material	Established for commonly used thermoformed plastic material	Established for commonly used thermoformed plastic material

Characteristic	Dentti System – K151965	Invisalign System – K081960	Clear Image™ Aligners – K071970	ClearCorrect System – K113618
Worn at Night	Yes	Yes	Yes	Yes
Rx or OTC	Rx	Rx	Rx	Rx