December 3, 2020

Braces on Demand, Inc
% Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K201940
Trade/Device Name: Braces on Demand Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: DYW, PNN
Dated: October 23, 2020
Received: October 28, 2020

Dear Patsy Trisler:

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,

Michael Adjodha, M.ChE.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K201940

Device Name

Braces on Demand Bracket

Indications for Use *(Describe)*

The Braces on Demand Bracket is intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.

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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K201940

510(k) Summary

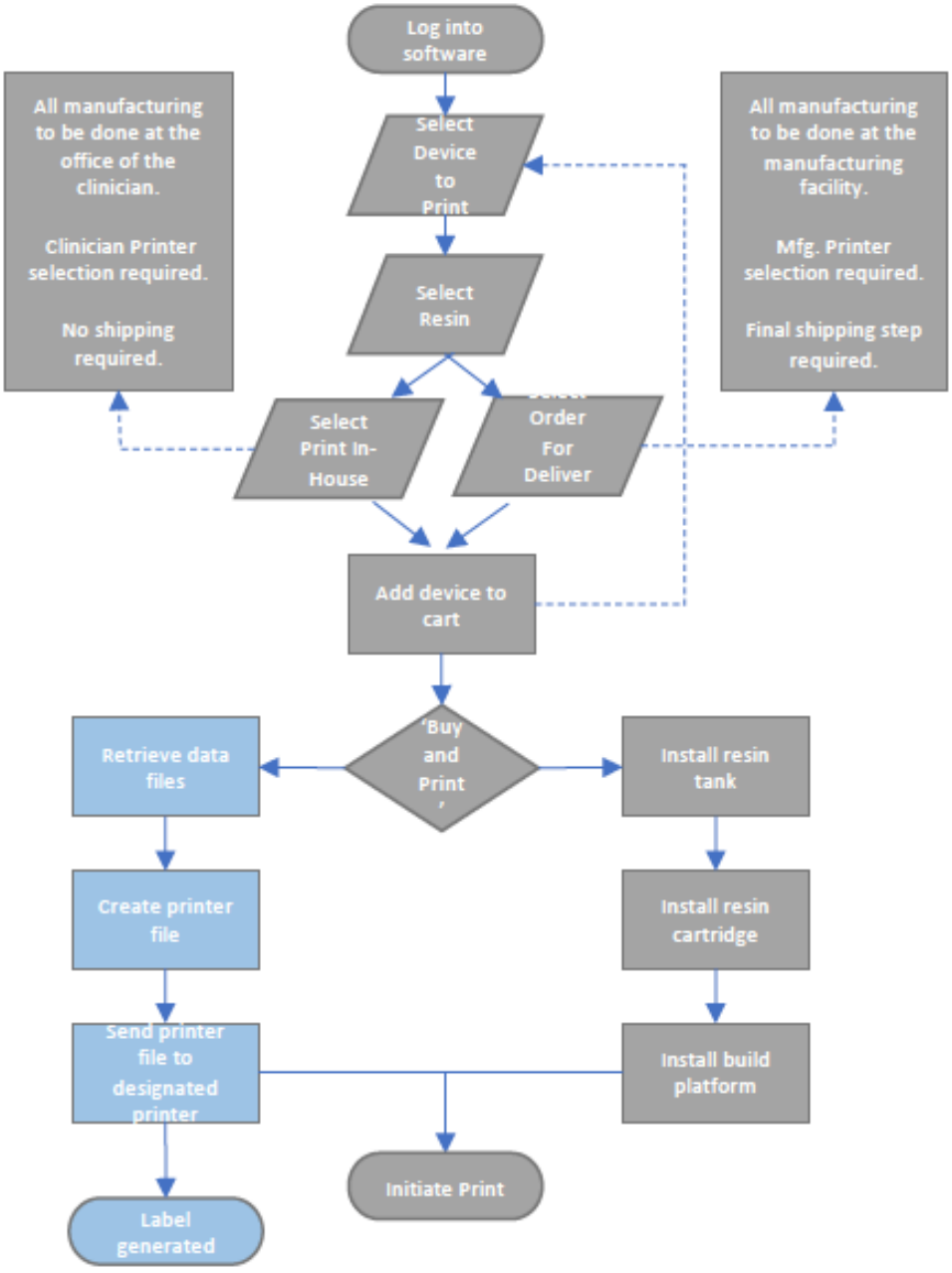
Submitter Name:	Braces on Demand, Inc.
Submitter Address:	422 South Broadway, Suite 203 Hicksville, NY 11801
Email Address: Telephone:	colin.corey@bracesondemand.com (516) 477-8377
Contact Person:	Colin Corey CEO
Date Prepared:	July 8, 2020
Device Trade Name:	Braces on Demand Bracket
Common Name	Orthodontic Plastic Bracket, Orthodontic Software

Predicate Devices

	Predicate A	Predicate B
Classification Name	Orthodontic Plastic Bracket	Orthodontic Software
Number	21 CFR 872.5470	21 CFR 872.5470
Product Code	DYW	PNN
Regulatory Class	2	2
Predicate Name	K140807, Composite Brackets, Ortho Specialties, Inc.	K180941, 3Shape Ortho System™; 3Shape A/S

Reference Device	K172398, Dentca Denture Teeth, Denterprise International, Inc.
Indications for Use Statement:	The **Braces on Demand Bracket System** is intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.
Device Description and Summary of Technological Characteristics	The proposed device is a 3D-printed bracket system that directly bonds to either primary teeth, permanent teeth, or mixed dentition to provide for orthodontic treatment for patients with malocclusions. Each bracket is 3D printed using a photopolymer denture resin. The **Braces on Demand Bracket System** has an integral hook design, which allows for attachment of accessories such as elastics or springs to assist the clinician in producing the desired tooth movement. The hook position on the Braces on Demand brackets can be on the mesial occlusal tiewing or the distal occlusal tiewing, similar to traditional orthodontic brackets. The application and removal of the Braces on Demand brackets are similar to other orthodontic brackets in that it requires orthodontic adhesive for bonding and standard orthodontic tools and techniques for de-bonding. The bonding surface of the bracket is a mechanical dovetail undercut design, allowing the bracket to mechanically retain the adhesive and bond to the facial surface of the tooth.

The Braces on Demand manufacturing process flowchart



Equipment and software validated for printing and post-printing processing:

	Brand	***Model***	***Type***
Printing Systems:	Formlabs	Form 3	SLA
	Formlabs	Form 2	SLA
Software Systems:	Formlabs	PreForm	Printer software
	Formlabs	Dashboard	Print monitoring software
Post Processing Systems:	Formlabs	Form Wash	Agitation cleaning system
	Formlabs	Form Cure	UV post curing system

Mechanism of Action

Based on a clinician's treatment plan, each bracket is used as prescribed to exert the force required for movement of the teeth.

Device Testing

Laboratory Testing

Bond Strength and Hook Strength testing were performed on the **Braces on Demand Bracket System** and compared to the predicate device was found to be substantially equivalent.

Dimensional Analysis and Dimensional Stability Tests were performed on the **Braces on Demand Bracket System** to validate the manufacturing process and prove the design inputs match the manufacturing outputs.

Software verification and validation testing was performed according to FDA's published guidance documents and supporting documents submitted in this 510(k) based on the software being of "Minor Level of Concern".

Biocompatibility

The following ISO 10993 testing was performed according to Good Laboratory Practices to assess the safety and biocompatibility of the plastic material:

Part 5 (Cytotoxicity Elution - MEM),

The reference device, utilizing the same exact materials and processes, also underwent the following testing:

Part 10 (Intracutaneous/Intradermal) Reactivity),
Part 10 (Maximization for Delayed-Type Hypersensitivity),
Part 11 (Subacute Systemic Toxicity)

This testing has shown that the material is safe and biocompatible for the stated intended use.

Animal | Human Testing

No animal or human testing are required for this product because it is composed of the same materials, is designed similarly, and is manufactured by method similar to the predicate device.

Comparison to Predicate Devices: The **Braces on Demand Bracket System**, compared to the two predicate devices:

- The intended use is the same.
- The mechanisms of action (software and bracket systems) are similar.
- The material used to make the brackets is similar to the predicate and is produced in the same manner (by additive manufacturing) as the reference device.
- The software used during the manufacturing processes is similar.

Substantial Equivalence Conclusion: Based on the documentation presented in the 510(k), as summarized above, it can be concluded that this software system and the produced brackets are substantially equivalent to the predicate devices.

Table A
Substantial Equivalence Summary – Predicate A

Element	Braces on Demand Bracket (*Proposed Device*)	Ortho Specialties Bracket (*Predicate Device*)	Comparison
Company	**Braces on Demand Inc.**	Ortho Specialties Inc.	N/A
510(k)	**To be Assigned**	K140807	N/A
Indications for Use	**The Braces on Demand Brackets are intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.**	The Composite Brackets are intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.	Indicated for the same purpose – movement of teeth.
Target Users	**Dental Professionals trained in orthodontics.**	Dental Professionals trained in orthodontics.	Same
Appliance Material	**Biocompatible plastic, photopolymer**	Biocompatible plastic, polycarbonate	Same category of biocompatible plastic. Difference in manufacturing method – Braces on Demand photopolymer is meant for 3D Printing and the Ortho Specialties polycarbonate is meant for injection molding.
Features	**Clear (translucent tooth tone) bracket system**	Clear (translucent) bracket system	Both brackets systems offer an aesthetic treatment option, the Braces on Demand system is more tooth tone with some transparency, the Ortho Specialties is more transparent with some minor white coloring.

Mode of use	**Archwire implementation by dental professional's technique**	Archwire implementation by dental professional's technique	Same
Physical Properties	**Mechanical Retention base eliminated need for plastic condition pre-treatment. Tooth position printed on bracket for identification.**	Mechanical Retention base eliminated need for plastic condition pre-treatment. Non-toxic ink on brackets for identification.	Same mechanical retention base. Tooth position identification is directly printed into the part with Braces on Demand brackets, eliminating the need for ink dots.
Application	**Bonded**	Bonded	Same
Manufacturing Method	**3D Printed**	Molded, thermoformed	Braces on Demand brackets utilize an additive manufacturing process (3D Printing) to create the finished, isotropic shape layer by layer. The Ortho Specialties Bracket utilized plastic injection molding to transform the molten plastic into the final desired shape.

Table B
Substantial Equivalence Summary – Predicate B

Element	Braces on Demand Bracket (*Proposed Device*)	3Shape Ortho System (*Predicate Device*)	Comparison
Company	**Braces on Demand Inc.**	3Shape Inc.	N/A
510(k)	**To be Assigned**	K180941	N/A
Indications for Use	**The Braces on Demand Brackets are intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.**	Ortho System™ for dental retainers and dental cast for sequential aligners is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options based on 3D models of the patient's dentition before the start of an orthodontic treatment.	The 3Shape system is designed around using removable clear aligners, whereas the Braces on Demand system is designed around using direct bonded appliances (brackets). Both systems utilize tools to manage appliances, and fabricate said appliances using 3D printers with STL file formats.
Target Users	**Dental Professionals trained in orthodontics.**	Dental Professionals trained in orthodontics.	Same

Appliance Material	**Medical grade plastic, photopolymer**	Medical grade plastic, thermoformed (K062828)	Same category of medical plastic. Difference in manufacturing method – Braces on Demand photopolymer is meant for 3D Printing and the 3Shape aligner material is meant for thermoforming after a 3D printed model is created.
Features	**Clear (translucent tooth tone) bracket system**	Clear (translucent) removable retainer	Both systems offer an aesthetic treatment option, the Braces on Demand system is direct bonded to the tooth while the 3Shape system is removable.
Mode of use	**Computer Application, for clinician to specify and design the medical device for manufacturing**	Computer Application, for the clinician to specify and design the series of medical devices for manufacturing	Similar applications, the difference is in the nature of direct bonded appliances of Braces on Demand vs. the removable clear aligners of 3Shape
Physical Properties	**Direct bonded appliance.**	Removable appliance does not require any bonding.	Different method of action, the direct bonded appliance of Braces on Demand vs. the removable clear aligner of 3Shape.
Virtual planning of orthodontic treatments simulating tooth movements	**No**	Yes	No simulated tooth movement is necessary for traditional direct bonded appliances.
Stereolithography (STL file format)	**Yes**	Yes	Same
Manufacturing Method	**3D Printed**	3d Printed, then thermoformed	Braces on Demand brackets utilize an additive manufacturing process (3D Printing) to create the finished, isotropic shape layer by layer. The 3Shape Ortho System utilizes 3D printing of models, and subsequent thermoforming to create the sequential clear aligners.