November 12, 2019

World Class Technology Corporation
℅ Alyssa Thomas
Principal Consultant
Allegiance Regulatory Consulting LLC
16642 SW Lansford Ct.
Beaverton, Oregon 97007

Re: K192202
Trade/Device Name: Clear21
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: August 9, 2019
Received: August 14, 2019

Dear Alyssa Thomas:

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 Nandkumar, Ph.D.
Acting 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)*
K192202

Device Name

Clear21™

Indications for Use *(Describe)*

The Clear21™ orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment.

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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This summary of 510(k) information is being submitted in accordance with the requirements of SMDA (Safe Medical Devices Act) 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K192202**

5.1. Submitter Contact Information

Name:	World Class Technology Corporation
Address:	1300 NE Alpha Drive McMinnville, OR 97128, USA
Phone:	503-472-8320
Fax:	503-435-2432
Contact:	Alan Kozlowski

Date Prepared:	November 11, 2019

5.2. Device Identification

Trade Name:	Clear21™
Common Name:	Orthodontic Ceramic Bracket
Classification Name:	Orthodontic Plastic Bracket
Regulatory Class:	872.5470
Product Code:	NJM

5.3. Legally Marketed Predicate Device(s)

Predicate Device: K081415 Ormco Corporation's Damon 4Clear (currently marketed as "Damon Clear" and "Damon Clear2")

Reference Device: K173440 Ortho Organizers, Incorporated/Henry Schein Orthodontics' Carriere SLX 3D Clear

5.4. Device Description

The Clear21™ orthodontic ceramic bracket system from World Class Technology Corporation is a system of aesthetic passive self-ligating brackets for fixed appliance orthodontic treatment. The brackets are bonded directly to patient's teeth of the

maxillary arch. The self-ligating mechanism (i.e. the door) eliminates the need for elastomeric and steel ligatures. The system is intended for use with clinician chosen orthodontic auxiliary devices.

5.5. Intended Use/Indications for Use

The Clear21™ orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment.

5.6. Summary of Technological Characteristics

The Clear21 bracket system includes brackets designed to provide the aesthetic benefit of clear ceramic materials with the function of traditional metal brackets. The brackets are available for the upper maxillary teeth from the second bicuspid to the second bicuspid, i.e. 5 to 5. The bracket body and door are ceramic injection molded. The three-component bracket assembly includes the bracket body, door and a spring. The Clear21 bracket is similar in materials, design, manufacturing processes and principles of operation as the predicate device (Damon Clear/Clear2). There are no significant differences between the Clear21 device and the predicate. A table comparing the key features of the subject device and the predicate device is provided below (Table 5-1Table 5-1).

Table 5-1 Subject & Predicate Device Comparison

	Clear21 **(Subject Device)**	**Damon Clear / Damon Clear2** **(K081415)**
Manufacturer / Marketing Company	World Class Technology Corporation	Ormco Corporation
Intended Use / Indication for Use	The Clear21™ orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment.	The Damon 4Clear* is a ceramic bracket system intended to aid in the movement of patient teeth during orthodontic treatment. * Name at the time of submission
Clinical Application	Orthodontic Treatment	Orthodontic Treatment
Clinical Setting / Site of Use	Prescription Device for Orthodontic Clinic Use	Prescription Device for Orthodontic Clinic Use

	Clear21 **(Subject Device)**	**Damon Clear / Damon Clear2** **(K081415)**
Target User	Dental professionals trained in orthodontic treatment	Dental professionals trained in orthodontic treatment
Technology Characteristics		
Device Materials	Polycrystalline Alumina & Nitinol	Polycrystalline Alumina & Nitinol
Device Design	Three-component construction comprised of a ceramic door & body with a nitinol spring element. The spring provides force for the ligating mechanism	Three-component construction comprised of a ceramic door & body with a nitinol spring element. The spring provides force for the ligating mechanism
Bracket Base Design	Base designed for direct bonding to the facial surface of the teeth. The bracket bonding pad/base includes mechanical retention features that are formed in the ceramic material	Base designed for direct bonding to the facial surface of the teeth. The bracket bonding pad/base utilizes mechanical retention features that are laser cut into the ceramic material
Bracket Hook Feature	Select brackets include an integrated hook for accessory attachment	Select brackets include an integrated hook for accessory attachment
Ligation Method	Self-Ligating	Self-Ligating
Bracket Identification	Color-coded Dots	Color-coded Dots
Manufacturing Method	- Ceramic Injection Molded - Processed Pad/Base - Spring Cut from Flat Stock. - Component Assembly	- Ceramic Injection Molded - Laser-Etch Pad/Base - Spring Formed into a Tubular Split Pin - Component Assembly
Functional Dimension (Prescription)		
In-Out	0.0265” – 0.0385”	0.03” – 0.040”
Torque	-11 deg. through +12 deg.	-11 deg. through +22 deg.
Angulation	2 to 9 deg.	2 to 9 deg.
Rotation	None of the brackets in the system incorporate rotation	None of the brackets in the system incorporate rotation

	Clear21 **(Subject Device)**	**Damon Clear / Damon Clear2** **(K081415)**
Principles of Operation		
Mode of Use	An archwire, selected by the clinician, is inserted into the archwire slots in the brackets and the ligating door is closed, securing the archwire in the slot. The archwires provide the forces needed to move the teeth in accordance with the dental professional's goals and technique.	An archwire, selected by the clinician, is inserted into the archwire slots in the brackets and the ligating door is closed, securing the archwire in the slot. The archwires provide the forces needed to move the teeth in accordance with the dental professional's goals and technique.
Application	Bracket pad/base is directly bonded to the facial surface of the tooth using typical orthodontic adhesives and bonding techniques	Bracket pad/base is directly bonded to the facial surface of the tooth using typical orthodontic adhesives and bonding techniques

5.7. Performance Data

Non-Clinical Testing – The application includes detailed discussions of nonclinical testing. In all instances, the Clear21 bracket device preformed as intended. Biocompatibility testing was also performed, demonstrating that the bracket materials and processing are acceptable based on the contact category for the Clear21 brackets. Functional testing was done to compare the Clear21 bracket's performance to that of its predicate and reference devices. A reference device, the Carriere SLX bracket, was used to compare the bond strength performance of the Clear21 bracket. The predicate device incorporates a unique proprietary bond base and the reference device uses a bond base design similar to the Clear21 and is more consistent with typical bond base designs. The ligation mechanism, structural integrity and bond strength of the Clear21 bracket are similar to the predicate and reference devices, as demonstrated through the results of functional testing. The Clear21 bracket produces similar results for ligating door open/close force range values, door pull-out, rotational strength, hook strength and bond strength. The nonclinical evaluations provide evidence of the Clear21 bracket's safety and effectiveness when used as intended.

Clinical Testing - Clinical testing is not included in this submission

5.8. Substantial Equivalence

The Clear21 brackets are as safe and effective as the predicate, the Damon Clear/Clear2. The Clear21 bracket system has the same indications for use as the predicate device. Clear21 has similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the Clear21 brackets and its predicate device raise no new or different issues of safety or effectiveness, as evident by the comparison testing. The performance data demonstrates that the Clear21 brackets are as safe and effective as the Damon Clear/Clear2 brackets. Thus, the Clear21 is substantially equivalent.

5.9. Conclusions

Conclusions drawn from the comparison to the predicate device and the nonclinical testing demonstrate that the Clear21 ceramic bracket system is as safe, as effective, and performs as well as the predicate device.