November 25, 2022

DentCare Dental Lab Pvt Ltd.
℅ Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Drive,
Suite 114
Aurora, Illinois 60504

Re: K222918
Trade/Device Name: DentCare Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 23, 2022
Received: September 26, 2022

Dear Manoj Zacharias:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222918

Device Name

DentCare Aligners

Indications for Use *(Describe)*

DentCare Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion. The aligner guide teeth to their final position by way of continuous gentle forces.

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.

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510K SUMMARY

K222918

As required by 21CFR§807.92(c)

A. APPLICANT INFORMATION

Applicant	DentCare Dental Lab Pvt Ltd.
Address	NAS Road, 130 Jn. Muvattupuzha, Ernakulam Kerala- 686661, India
Phone	91 4852835112
Fax	---------
E-mail	info@dentcaredental.com
Contact Person	Mr. Abin Johns Raju
Designation	Head R & D
Contact Number	91 9072666345
Contact Email	abinjohns@dentcaredental.com
Date Submitted	23 September 2022

B. DEVICE IDENTIFICATION

Name of the device	DentCare Aligners
Product proprietary or trade name	
Common or usual name	Aligner, Sequential
Regulation name	Orthodontic Plastic Bracket
Device Classification	Class II
Product Code	NXC
Regulation Number	21 CFR 872.5470
Review Panel	Dental

C. PREDICATE DEVICE

Legally Marketed devices that Equivalency is claimed	Clear Aligner
510(K) Number	K210373
Regulatory Class	Class II
Product code	NXC

D. REFERENCE DEVICE

This reference device- 3 Shape Ortho System ™ is the software which used for the manufacturing process of DentCare Aligners.

Sponsor	3Shape A/S
Device Name & Model	Ortho System™
510 (K) Number	K180941
Product Code	PNN (Orthodontics Software)
Regulation Number	21 CFR 872.5470
Regulation Class	Class II

E. DESCRIPTION OF THE DEVICE:

The DentCare Aligners are transparent medical grade thermoplastic materials moulded for the use in orthodontic alignment of teeth from one position to another. The DentCare Aligners are used in correcting various malocclusions. Hence it requires precise treatment planning before fabrication. Thorough understanding of the process and steps are required before proceeding to provide a successful aligner treatment.

F. INDICATIONS FOR USE/INTENDED USE OF THE DEVICE:

DentCare Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion. The aligner guide teeth to their final position by way of continuous gentle forces.

G. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristics	**Device Performance**		**Remarks**
	Predicate Device	**Subject Device**	
510(K) Number	K210373	K222918	---
Name of device	Clear Aligner	DentCare Aligners	Similar
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Regulation Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	Same
Class	Class II	Class II	Same
Indications for use	This device is indicated for use in the alignment of all permanent dentition through orthodontic treatment of misalignment and malocclusion	DentCare Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion. The aligner guide teeth to their final position by way of continuous gentle forces.	Similar
Prescription or OTC	Prescription Use	Prescription Use	Same
Materials	Co-polyester or Co-polymer	Co-polyester or Co-polymer	Same
Mode of Action	Continuous gentle force applied to teeth to achieve movement	Continuous gentle force applied to teeth to achieve movement	Same

Characteristics	Device Performance		Remarks
	Predicate Device	Subject Device	
510(K) Number	K210373	K222918	---
Manufacturing Method	Thermoforming	Thermoforming	Same
Patient Removable	Yes	Yes	Same
Single use/Reuse	Repeated use by a single patient	Repeated use by a single patient	Same
Duration of Use	20-22 hours per day	20-22 hours per day	Same
Software Use	Yes	Yes	Same
Sterility	Non Sterile	Non Sterile	Same
Biocompatibility			
Primary Skin Irritation-ISO 10993	Passed the tests as per ISO 10993-10:2010 (E)	Passed the tests as per ISO 10993-23:2021	Similar
Dermal Sensitization-ISO 10993-10:2010(E)	Passed the tests as per ISO 10993-10:2010 (E)	Passed the tests as per ISO 10993-10:2010 (E)	Same
In vitro cytotoxicity-ISO 10993-5:2009(E)	Passed the tests as per ISO 10993-5:2009(E)	Passed the tests as per ISO 10993-5:2009(E)	Same
Acute systemic toxicity- ISO10993-11-2017(E)	No data available	Passed the tests as per ISO10993-11-2017(E)	-----

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods.

H. NON-CLINICAL TESTING SUMMARY

Due to the difficulty in evaluating this type of dental device in a laboratory environment, no direct performance bench testing of the clear aligner was performed. The device material tested to the following standards and meets the acceptance criteria.

- Density (g/cm^3) ASTM D1505
- Water absorption 24 h/23^0C (%) ASTM D570
- Tensile Strength (Mpa) ASTM D882
- Elongation at Break (%) ASTM D882
- E-modulus (Mpa) ASTM D882

Performance Data:

PROPERTIES	GUIDLINE	VALUE OBTAINED
Density	ASTM D1505	1.19 g/cm^3
Water absorption, 24 h/23^{0}C	ASTM D570	0.5%
Tensile Strength	ASTM D882	41 MPa
Elongation at Break	ASTM D882	179%
E-modulus	ASTM D882	1462 MPa

I. CLINICAL TESTING SUMMARY

Not applicable - Clinical data is not needed for most devices cleared by the 510(K) process.

J. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrate that the subject device in 510(K) submission DentCare Aligners are safe, as effective and performs as well as the legally marketed predicate device cleared under K210373.

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