November 3, 2022

Graphy Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K223355
Trade/Device Name: Tera Harz Clear
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: October 30, 2022
Received: November 2, 2022

Dear Dave Yungvirt:

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 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)*
K-223355

Device Name
TERA HARZ CLEAR

Indications for Use *(Describe)*
TERA HARZ CLEAR is intended for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force. TERA HARZ CLEAR is intended exclusively for professional dental work. Fabrication of aligner with TERA HARZ CLEAR requires an additive manufacturing system (AMS) that includes compatible with the following:

	Brand	Type
Design:		
Scanner	3Shape A/S	TRIOS 3 Basic
Design software	3Shape A/S	3Shape Ortho System™
Printing:		
3D Printer	UNIZ	SLASH 2
	SprintRay Inc.	SprintRay Pro 95
Post-Curing:		
Post-cure unit	CureM	U102H

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.

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K223355

510(k) Summary
For
TERA HARZ CLEAR

I. SUBMISSION SPONSOR

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II. SUBMISSION CORRESPONDENT

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Contact: Kyung-hwan Kim, Representative Consultant, QA
Email: info@smbkorea.com

III. DATE PREPARED

October 20, 2022

IV. DEVICE

Trade or Proprietary Name: TERA HARZ CLEAR
Common or Usual Name: Sequential Aligner
Classification Name: Orthodontic plastic bracket (872.5470)
Regulatory Class: II
Product Code: NXC
Classification Panel: Dental

V. PREDICATE DEVICE

Primary Predicate Device:
K180107, Blue Sky Bio Aligner/ Blue Sky Bio LLC (Class II)
Referencee Device
Dental LT Clear Resin (V2)/ Formlabs Inc. (Class I)

DEVICE DESCRIPTION
TERA HARZ CLEAR is a series of clear aligners that are used to replace traditional

orthodontic wires and brackets for the alignment of maloccluded or misaligned teeth.

This series of aligner is intended for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars) by moves the teeth gently, and in small increments, from their original to their final treated position for improved dental alignment. This series of aligner is worn for approximately 1 week of 20 to 22 hours per day after (However, there are to be removed for eating and for cleaning) which it is replaced by the next stage aligners and are designed to be used in a sequence. This is repeated for duration as prescribed by the dental clinician.

TERA HARZ CLEAR is a light-cured, methacrylate-based resin commonly can used in additive manufacturing for the production of dental structures such as sequential aligners.

TERA HARZ CLEAR has stored in a black 1,000 g of HDPE bottle. It contains materials with colors of yellowish. This device is a liquid photo-curable material that is polymerized by UV laser at 405~412 nm. It can be used to make a tooth model with a photo-curable polymer that is cured by ultraviolet light. The liquid UV curing resin is cured at a specific wavelength (395~405 nm) by the photo-initiator contained in the resin. It is typically 100 µm in thickness and is output at a resolution of 40 to 90 µm on the x, y axis, and it is possible to produce three-dimensional printed matter by curing lamination step by step a thickness of 100 µm.

However, scanner, design software, 3D printer and post-cure unit are not included with the device.

These fabrications of TERA HARZ CLEAR are beginning with the dental clinician prescribing aligners to treat a patient's malocclusion, and decision to use methacrylate-based resins is made by the dental clinician. TERA HARZ CLEAR, an orthodontic appliance such as sequential aligner, is manufactured in a 3D printer that is compatible.

The dental clinician can generate a digital file by scanning the patient's mouth directly using listed with Intraoral scanner under FDA Classification Product Code NOF, regulation 872.3661.

This digital file is a series of CAD files (.stl) for building models that can be used to fabricate aligners. Commonly used standard dental software is used by dental professionals to virtually design a sequential aligner and generate an industry-standard "STL" 3D dataset which reflects the intended shape and contour. The design software used is 3Shape Ortho System™ by 3Shape A/S (K180941). The specialized orthodontic treatment planning software has a 510k clearance for the intended use under FDA

Classification Product Code PNN, regulation 872.5470. This software is used for management of 3D scanned orthodontic models, orthodontic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating tooth movements, and design of sequential aligners based on 3D scanned orthodontic models.

Once dental clinic manufacturing unit receive the data that *.stl CAD files of the treatment plan the 3D printer begins additive manufacturing. The dental clinician generates sequential 3D printed models replicating the approved treatment plan. The sequential aligner is 3D printed and cured in a post-cure unit. The fabricated aligners are cut to fit dentition, the cleaned and polished to remove rough edges by the dental clinician. The prescribing physician review and approves the sequential aligners are provides them to the patient the confirming fit and design.

VI. INDICATION FOR USE

TERA HARZ CLEAR is intended for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force. TERA HARZ CLEAR is intended exclusively for professional dental work. Fabrication of aligner with TERA HARZ CLEAR requires an additive manufacturing system (AMS) that includes compatible with the following:

	Brand	**Type**
Design:		
Intraoral scanner	3Shape A/S	TRIOS 3 Basic
Design software	3Shape A/S	3Shape Ortho System™
Additive Manufacturing System:		
3D Printer	UNIZ	SLASH 2
	SprintRay Inc.	SprintRay Pro 95
Post-Curing:		
Post-cure unit	CureM	U102H

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The indications for use and mechanism of action of subject device is identical to the predicate device and supports a determination of substantial equivalence.

However, there is a main difference in the predicate device because the materials of use and the manufacturing process are differed.

So, Dental LT Clear Resin (V2) is selected as a reference device to support method of processing and raw material.

So that, TERA HARZ CLEAR performed testing as that of each predicate device. All test results of Flexural Strength, Flexural Modulus,Water Solubility, and Water Sorption was similar to that of the predicate device that meet the requirements of ISO 20795-2:2013.

The performance characteristics of the TERA HARZ CLEAR are comparable to those of the predicate device for this particular indication and raise no new or different questions of safety and effectiveness. Therefore, the subject device and the predicate device are substantially equivalent in physical properties.

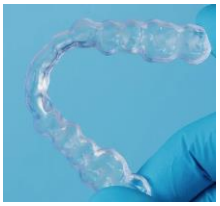
Any differences in technology characteristics are accompanied by information that demonstrated the device is as safe and as effective as the predicate device and do not raise different questions of safety and effectiveness than the predicate.

It was concluded, therefore, that the technological differences do not raise different questions of safety and effectiveness.

	SUBJECT Device	**Primary PREDICATE Device (K180107)**	**REFERENCE Device**	**Significant Difference**
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Trade Name	TERA HARZ CLEAR	Blue Sky Bio Aligner	Dental LT Clear Resin (V2)	–
Device Classification Name	aligner, sequential	aligner, sequential	MAINTAINER, SPACE PREFORMED, ORTHODONTIC	–
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5525	Predicate device : same Reference device : different
Product Code	NXC	NXC	DYT, KMY	Predicate device : same Reference device : different.
Class	II	II	I	Predicate device : same Reference device : different.

	SUBJECT Device	Primary PREDICATE Device (K180107)	REFERENCE Device	Significant Difference
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Indications for Use	TERA HARZ CLEAR is intended for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force. TERA HARZ CLEAR is intended exclusively for professional dental work. Fabrication of aligner with TERA HARZ CLEAR requires an additive manufacturing system (AMS) that includes compatible with the following:	Blue Sky Bio Aligners are a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force.	Dental LT Clear Resin (V2) enables dental practices and labs to rapidly manufacture a range of dental products in-house, from biocompatible surgical guides and splints to fixed prosthetic and clear aligner models.	Similarities: Indications for use of the subject device is slightly different from the predicate device in phrase but fundamental indication is the identical. However, the reference device is different.
Mechanism of Action	Orthodontic tooth movement occurs through forces applied to the teeth by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional's prescription.	The mechanism of action is similar to the predicate devices and supports a determination of substantial equivalence. Orthodontic tooth movement occurs through forces applied to the teeth by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional's prescription	Unknown	Similarities: Mechanism of action of the subject device is identical from the predicate device. however, reference device is unknown.

	SUBJECT Device	Primary PREDICATE Device (K180107)	REFERENCE Device	Significant Difference
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
In Use Duration	Aligners are worn for approximately 1 week of 20-22 hours of wear per day, after which itis replaced by the next stage aligners. This is repeated for duration as prescribed by the dental clinician.	Unknown	Unknown	Difference: Because the predicate device and reference device are unknown, we concluded that the predicate device and the subject device are different.
Materials of Use	Methacrylate-based resins	Essix Thermoplastic	Methacrylate-based resins	Difference: The predicate device and subject device is different. However reference device is similar in Methacrylate-based resins. so Dental LT Clear Resin(V2) is selected as a reference device to support raw material.
Manufacturing Technology	Additive	Thermoforming	Additive	Difference: The predicate device and subject device is different. since there are no products in the market that have the same manufacturing process as our aligners, Dental LT Clear Resin (V2) is selected as a reference device to support manufacturing process.

	SUBJECT Device	Primary PREDICATE Device (K180107)	REFERENCE Device	Significant Difference
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Design				Similarities: The arch shape does not introduce any additional safety or efficacy concerns. Dimensions of the arch form are in the same range.
Performance Testing	ISO 20795-2:2013	Does not apply.	ISO and ASTM	Similarities: This does not introduce additional safety or efficacy concerns because subject device and predicate device meet some requirements from ISO 20795-2:2013.
Surface characteristics	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) The surface of the sample was smooth, hard and glossy;	The surface of the sample was smooth, hard and glossy.	Unknown	Similarities: The specifications of predicate device are in the same range. This minor variance does not introduce additional safety or efficacy concerns because both devices meet requirements from ISO 20795-2:2013.

	SUBJECT Device	Primary PREDICATE Device (K180107)	REFERENCE Device	Significant Difference
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Shape capability	Testing of 5 samples, same lot with 2 kinds of 3d printer(UNIZ Slash2 , SprintRay pro95) Sample edges were reproduced;	Sample edges were reproduced.	Unknown	Similarities: The specifications of predicate device are in the same range. This minor variance does not introduce additional safety or efficacy concerns because both devices meetrequirements from ISO 20795-2:2013.
Colour	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) The color was expressed transparently without changing;	The color was expressed transparently without changing.	Unknown	Similarities: The specifications of predicate device are in the same range. This minor variance does not introduce additional safety or efficacy concerns because both devices meetrequirements from ISO 20795-2:2013.

	SUBJECT Device	Primary PREDICATE Device (K180107)	REFERENCE Device	Significant Difference
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Freedom from porosity	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) There is no porosity;	There is no porosity.	Unknown.	Similarities: The specifications of predicate device are in the same range. This minor variance does not introduce additional safety or efficacy concerns because both devices meet requirements from ISO 20795-2:2013.
Ultimate Flexural Strength (≥5 MPa)	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) Uniz Avg. 5.91 MPa; SprintRay pro 95 Avg. 6.04 MPa	Avg. 5.17 MPa	Unknown	Similarities: The ultimate flexural strength of subject device is equivalent to or better than the predicate device because the average value of the subject device' ultimate flexural strength was statistically significantly higher than that of the predicate device. This minor variance does not introduce additional safety or efficacy concerns because both devices meet requirements from ISO 20795-2:2013.

	SUBJECT Device	**Primary PREDICATE Device (K180107)**	**REFERENCE Device**	**Significant Difference**
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Flexural modulus (≥50 MPa)	Testing of 5 samples, same lot with 2 3d printer (UNIZSlash2 , SprintRay pro 95) Uniz Avg. 69.10 MPa; SprintRay pro 95 Avg. 72.37 MPa	Avg. 56.26 MPa	Unknown	Similarities: The ultimate flexural strength of subject device is equivalent to or better than the predicate because the average value of the subject device' ultimate flexural strength was statistically significantly higher than that of the predicate device. This minor variance does not introduce additional safety or efficacy concerns because both devices meet requirements from ISO 20795-2:2013.

	SUBJECT Device	Primary PREDICATE Device (K180107)	REFERENCE Device	Significant Difference
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Solubility (≤5 µg/mm³)	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) Uniz Avg. 1.53 µg/mm³; SprintRay pro 95 Avg. 1.55 µg/mm³	Avg. 1.67 µg/mm³	Unknown	Similarities: The specifications of predicate device are in the same range. This minor variance does not introduce additional safety or efficacy concerns because both devices meet requirements from ISO 20795-2:2013.
Water sorption (≤32 µg/mm³)	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) Uniz Avg. 17.44 µg/mm³; SprintRay pro 95 Avg. 17.02 µg/mm³	Avg. 17.51 µg/mm³	Unknown	Similarities: The specifications of predicate device are in the same range. This minor variance does not introduce additional safety or efficacy concerns because both devices meet requirements from ISO 20795-2:2013.

	SUBJECT Device	Primary PREDICATE Device (K180107)	REFERENCE Device (K203000)	Significant Difference
Manufacturer	**Graphy Inc.**	**Blue Sky Bio LLC**	**Formlabs Inc.**	**–**
Appearance	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) No evidence of foreign materials, contaminations,or any other defects that should be hazardous uponthe usage.	No evidence of foreign materials, contaminations,or any other defects that should be hazardous upon the usage.	Unknown	No difference.
Precision (The standard deviation is less than 0.150)	Testing of 5 samples, same lot with 2 kind of 3d printer(UNIZ Slash2 , SprintRay pro95) Uniz Avg.0.072/mm SprintRay pro 95 Avg.0.065/mm	Avg. 0.122/mm	Unknown	Similarities: The precision of subject device is equivalent to or better than the predicate device because the average value of the subject device' precision was statistically significantly lower than that of the predicate device.
Biocompatibility	Biocompatible according to ISO 10993-1	The material used for the Blue Sky Bio aligners has a 510k clearance as an aligner material ,so no biocompatibility testing was performed.	Biocompatible according to ISO 10993-1	No difference.
OTC or Rx	Rx	Rx	Rx	No difference.
Sterile	Not Applicable	Not Applicable	Not Applicable	No difference.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Manufacturing Validation

A manufacturing validation was performed to demonstrate the manufacturing process for TERA HARZ CLEAR.

An independent 3rd party software and digital calipers were used to perform point-to- point and critical displacement measurement. All translational measurements were within 0.150 mm of the target input value, the predefined tolerance of the manufacturing process. There were no statistical differences in the difference in the intended and measured values observed from any of the groups. This test has met the pre-established acceptance criteria.

And the test also conducted studies on the effect of manufacturing validation and material reuse on the properties of the final finished device according to FDA's published guidance documents, "Technical Considerations for Additive Manufactured Medical Devices".

The TERA HARZ CLEAR were outputted by each different output condition and each flexural strength were measured and the evaluation criteria of the all the specimens were more than 50 MPa. The optimal output condition is that the output angle is 30°, and the output position is centered to confirming that the optimal condition is to be output.

In addition, it was confirmed that there was no problem in the number of effective outputs for repeated material output up to 7 times.

Performance Testing

Bench testing was performed to ensure the accuracy of the final product carried through the entire process from the initial intraoral scan through treatment planning and manufacturing process of the final finished aligner.

In addition, bench testing was conducted on both the subject device and the predicate device (Blue Sky Bio Aligner, K180107) to evaluate critical properties including Flexural Strength, Flexural Modulus, Water Solubility, Water absorption and etc. All met the requirements of ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers.

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	Representative sample	**TERA HARZ CLEAR** (Model/type TC-85DAC) 3D Printer		**Blue Sky Bio Aligner**	
	Test Item	**UNIZ Slash 2**	**SprintRay PRO 95**	**Blue Sky Bio Aligner**	**Test criteria**
1.	Surface characteristics	Sample surface is smooth, hard and glossy.	Sample surface is smooth, hard and glossy.	Sample surface is smooth, hard and glossy.	surface is smooth, hard, and glossy
2.	Shape capability	Sample edges are reproduced.	Sample edges are reproduced.	Sample edges are reproduced.	edges are reproduced
3.	Colour	The color is expressed transparently without changing.	The color is expressed transparently without changing.	The color is expressed transparently without changing.	the color is expressed transparently without changing
4.	Freedom from porosity	There is no porosity.	There is no porosity.	There is no porosity.	there is no porosity
5.	Ultimate Flexural Strength (MPa)	Avg. 5.92	Avg. 6.02	Avg. 5.17	≥5 MPa
6.	Flexural modulus (MPa)	Avg. 69.10	Avg. 72.38	Avg. 56.26	≥50 MPa
7.	Solubility	Avg. 1.54	Avg. 1.56	Avg. 1.67	≤5 µg/mm^3
8.	Water sorption (≤32 µg/mm^3)	Avg. 17.45	Avg. 17.03	Avg. 17.51	≤32 µg/mm^3
9.	Precision	1) 0.079/mm 2) 0.075/mm 3) 0.069/mm 4) 0.068/mm 5) 0.071/mm	1) 0.063/mm 2) 0.069/mm 3) 0.065/mm 4) 0.071/mm 5) 0.059/mm	1) 0.102/mm 2) 0.139/mm 3) 0.108/mm 4) 0.137/mm 5) 0.125/mm	less than 0.15

As a result, TERA HARZ CLEAR tested with two types of 3D prints and predicate device met the tests criteria according to ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers.

The result of the performance comparison test demonstrates that TERA HARZ CLEAR is substantially equivalent to the predicate device in physical properties. Both devices meet requirements of ISO 20795-2:2013.

Biocompatibility

A biocompatibility discussion was conducted. The TERA HARZ CLEAR uses the methacrylate-based resin, and this material has been tested and shown to be compliant with the following standards:

- EN ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- EN ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing
- EN ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2013, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-11:2018, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

IX. CLINICAL DATA

Clinical performance data was not provided for TERA HARZ CLEAR.

X. CONCLUSIONS

The TERA HARZ CLEAR is very similar to the predicate device and demonstrate substantial equivalence to predicate device K180107 in physical properties.

An analysis for subject device compared to the predicate device show TERA HARZ CLEAR and the Blue Sky Bio Aligner meet the requirements of Manufacturing Validation, all two devices share the same product code, meet the requirements, and all two are biocompatible.

In addition, an analysis for subject device compared to the predicate device show TERA HARZ CLEAR and the Blue Sky Bio Aligner meet the requirements of ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers. All two devices meet or exceed the minimum strength requirements, and all two are biocompatible.

Any differences between subject device and the predicate device are material of use and method of processing. So reference device, which has same method of processing and is similar in material of use, is added to support material of use and method of processing.