February 24, 2023

Blue Sky Bio, LLC
% Nevine Erian
Regulatory Consultant
BQC Consulting, LLC
24341 Barbados Dr.
Dana Point, California 92629

Re: K221845
Trade/Device Name: Blue Sky Bio Aligner G & Blue Sky Plan S/W for Blue Sky Bio Aligner G
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC, PNN
Dated: January 24, 2023
Received: January 25, 2023

Dear Nevine Erian:

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 -S

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)*

K221845

Device Name

Blue Sky Plan Software for Blue Sky Bio Aligner G and Blue Sky Bio Aligner G

Indications for Use *(Describe)*

Blue Sky Plan software module for Blue Sky Bio Aligner G 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

Blue Sky Bio Aligner G is 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.

The use of the Blue Sky Bio Plan software module for Blue Sky Bio Aligner G requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary - K221845

Submitter	**Blue Sky Bio, LLC** 800 Liberty Drive Libertyville, IL 60048 Establishment Reg. No. 3003402534
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Official Correspondent	Nevine Erian Regulatory Consultant **BQC Consulting, LLC** 24341 Barbados Dr. Dana Point, CA 92629 **Phone** (949) 370-7155 **E-mail** nevine@bqcconsulting.com
Date Prepared	February 23, 2023

Trade/Device Name	Blue Sky Bio Aligner G & Blue Sky Plan Software for Blue Sky Bio Aligner G
Common Name	Sequential Aligner
Classification Names & Regulation Numbers	Aligner, Sequential – 21 CFR 872.5470 Orthodontic Software – 21 CFR 872.5470
Product Codes	NXC & PNN

Predicate Devices

Arcad SmileStudio and Arcad Aligner System (ArcadLab, LLC) – K192244 – ***Primary Predicate***

Blue Sky Bio Aligner (Blue Sky Bio, LLC) – K180107 – ***Reference Device I***

Tera Harz Clear (Graphy, Inc.) – K223355 – ***Reference Device II***

Device Description

The Blue Sky Bio Aligner G consists of a series of clear plastic aligner trays that offer a solution for aesthetic orthodontic treatment by utilizing a set of removable aligners to correct tooth malocclusions.

Blue Sky Bio Aligner G starts with the dental clinician prescribing aligners to treat a patient's malocclusion, and the decision to use a methacrylate-based resin for sequential aligners.

A dental clinician (e.g. orthodontist or dentist), using a standard personal computer prescribes the Blue Sky Bio Aligner G based on an assessment of the patient's teeth and determines the course of treatment, using Blue Sky Bio's Blue Sky Plan software (K180107). The clinician takes molds of the patient's teeth and completes a prescription form and sends the molds to the dental lab, which in turn scans the molds and uploads the .STL files of the molds in Blue Sky Plan software. This digital file is a series of CAD files (.STL) for building models that can be used to fabricate aligners. Alternatively, the dental clinician may generate the digital files by scanning the patient's mouth directly, using an intraoral scanner, and then sends the files to the dental lab.

The dental lab or the clinician designs a series of digital models and plastic trays intended to gradually realign the patient's teeth, using Blue Sky Plan software. The prescribing physician reviews and approves the model scheme before the aligners are produced. Once approved by the clinician, the dental lab produces the Blue Sky Bio Aligner G sequential aligners, which are 3D printed with a clear biocompatible resin.

The Blue Sky Bio Aligner G are sent to the dental clinician who then provides them to the patient, confirming fit and design. Over a period of time, additional trays are provided sequentially to the patient by the clinician to gradually move the target teeth to the designed position. The dental health professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at any time.

Indication for Use

Blue Sky Plan software module for Blue Sky Bio Aligner G 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

Blue Sky Bio Aligner G is 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.

The use of the Blue Sky Bio Plan software module for Blue Sky Bio Aligner G requires the user to have the necessary training and domain knowledge in the practice orthodontics, as well as to have received a dedicated training in the use of the software.

Material Composition

Blue Sky Bio Aligner G is composed of a methacrylate-based resin.

Technological Characteristics

Blue Sky Bio Aligner G is 3D printed with a photo-curable resin.

Non-Clinical Performance Testing

Blue Sky Bio Aligner G was tested and met the applicable requirements of ISO 20795-2:2013 – Dentistry – Base Polymers – Part 2: Orthodontic base polymers.

Bench test results allowed us to conclude that Blue Sky Bio Aligner G meets its intended use.

Biocompatibility

Blue Sky Bio Aligner G meets the biocompatibility requirements of the following standards:

- ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 7405:2018 Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry

Biocompatibility testing has shown that Blue Sky Bio Aligner G is safe and biocompatible for the stated intended use.

Clinical Performance Data

The performance of methacrylate-based resins in the clinical environment has been well established. No human clinical testing was performed to support the substantial equivalence of Blue Sky Bio Aligner G.

Substantial Equivalence

The technical characteristics of Blue Sky Bio Aligner G & Blue Sky Plan Software for Blue Sky Bio Aligner G are substantially equivalent to the predicate devices.

Material

Blue Sky Bio Aligner G is a resin-based material as the predicate devices.

Physical Properties

Blue Sky Bio Aligner G has similar physical properties as the primary predicate device.

Comparison to Predicate Devices

Attribute	Blue Sky Bio Aligner G & Blue Sky Plan S/W for Blue Sky Bio Aligner G	Arcad Aligner System & Arcad SmileStudio *(Primary Predicate)*	Blue Sky Bio Aligner *(Reference Device)*	Tera Harz Clear *(Reference Device)*
Indications				
Software 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.	Yes	Yes	Yes	No – Does not include software
Device is a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars).	Yes	Yes	Yes	Yes
Utilizing a series of incremental tooth movements, device sequentially positions teeth by way of continuous gentle force.	Yes	Yes	Yes	Yes
FDA Product Code	NXC & PNN	NXC & PNN	NXC	NXC

Attribute	Blue Sky Bio Aligner G & Blue Sky Plan S/W for Blue Sky Bio Aligner G	Arcad Aligner System & Arcad SmileStudio *(Primary Predicate)*	Blue Sky Bio Aligner *(Reference Device)*	Tera Harz Clear *(Reference Device)*
Physical & Clinical Properties				
Material Initial State	Liquid	Solid	Solid	Liquid
Material Type	Photo-curable resin	Thermoplastic Resin	Thermoplastic Resin	Photo-curable Resin
Device Type	Clear Plastic Aligners	Clear Plastic Aligners	Clear Plastic Aligners	Clear Plastic Aligners
Mode of Action	Orthodontic tooth movement through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
In Use Duration	Each aligner is worn for 2 weeks for 20-22 hours of wear per day	Each aligner is worn for 2 weeks for 20-22 hours of wear per day	Each aligner is worn for 2 weeks for 20-22 hours of wear per day	Each aligner is worn for 2 weeks for 20-22 hours of wear per day
Sterile	No	No	No	No
Single Use	No	No	No	No
Rx or OTC	Rx	Rx	Rx	Rx

Attribute	Blue Sky Bio Aligner G & Blue Sky Plan S/W for Blue Sky Bio Aligner G	Arcad Aligner System & Arcad SmileStudio *(Primary Predicate)*	Blue Sky Bio Aligner *(Reference Device)*	Tera Harz Clear *(Reference Device)*
Technical Attributes				
Chemical Characterization	Methacrylate-based resins with photo initiators	Polyurethane resins	Polypropylene/ethylene copolymer	Methacrylate-based resins with photo initiators
Fabrication Method	3D printed & cured	Vacuum Thermoformed	Vacuum Thermoformed	3D printed & cured
3 D Printer	SprinRay Pro 95	n/a	n/a	SprinRay Pro 95 & other printer
Curing Wavelength	405 nm	n/a	Not applicable	405 nm
Layer Thickness when Printing	100 µm	n/a	Not applicable	100 µm
Polymerization Method	Light Curing	n/a	Not applicable	Light Curing
Design Software Used	Blue Sky Plan for Blue Sky Bio Aligner G	Arcad SmileStudio	Blue Sky Plan for Blue Sky Bio Aligner	3Shape Ortho System™
Software Attributes				
Import of Digital Orthodontic Models	Import and management of digital orthodontic models from patient scans	Import and management of digital orthodontic models from patient scans	Import and management of digital orthodontic models from patient scans	No S/W included

Attribute	Blue Sky Bio Aligner G & Blue Sky Plan S/W for Blue Sky Bio Aligner G	Arcad Aligner System & Arcad SmileStudio *(Primary Predicate)*	Blue Sky Bio Aligner *(Reference Device)*	Tera Harz Clear *(Reference Device)*
Sequential Aligners Design	Uses a scan of tooth impression or a digital scan to generate the image of a final treated state and then interprets a series of images that represent intermediate teeth states. The software converts the files to produce a series of patient specific molds and converts the mold files into STL files for 3D printed aligners.	Uses a scan of tooth impression or a digital scan to generate the image of a final treated state and then interprets a series of images that represent intermediate teeth states. The S/W converts the files to produce the series of patient specific molds which are 3D printed, so aligners are vacuum thermoformed over the molds.	Uses a scan of tooth impression or a digital scan to generate the image of a final treated state and then interprets a series of images that represent intermediate teeth states. The S/W converts the files to produce the series of patient specific molds which are 3D printed, so aligners are vacuum thermoformed over the molds.	No S/W included
Digital Imaging Tools	Software is used as an aid to diagnosis and for treatment planning by the clinician	Software is used as an aid to diagnosis and for treatment planning by the clinician	Software is used as an aid to diagnosis and for treatment planning by the clinician	No S/W included

Attribute	Blue Sky Bio Aligner G & Blue Sky Plan S/W for Blue Sky Bio Aligner G	Arcad Aligner System & Arcad SmileStudio *(Primary Predicate)*	Blue Sky Bio Aligner *(Reference Device)*	Tera Harz Clear *(Reference Device)*
Teeth Segmentation	Segment individual teeth within the model to allow independent digital movement of the teeth	Segment individual teeth within the model to allow independent digital movement of the teeth	Segment individual teeth within the model to allow independent digital movement of the teeth	No S/W included
Planning of Orthodontic Treatments	Virtual planning of orthodontic treatments simulating tooth movements	Virtual planning of orthodontic treatments simulating tooth movements	Virtual planning of orthodontic treatments simulating tooth movements	No S/W included
Export of Data Format	Export data as Stereolithography (STL file format)	Export data as Stereolithography (STL file format)	Export data as Stereolithography (STL file format)	No S/W included
STL File Type	Export STL files of a layer of a defined thickness corresponding to the negative of a series of models. The STL files are intended to manufacture directly printed aligners	Export STL files for printing a series of models. The models are to be used as a basis for thermoformed aligners	Export STL files for printing of a series of models. The models are to be used as a basis for thermoformed aligners	No S/W included

The physical, chemical and technological differences between Blue Sky Bio Aligner G & Blue Sky Plan Software for Blue Sky Bio Aligner G and the predicate devices do not impact safety and effectiveness, as the finished clinical product is a biocompatible aligner regardless of the difference in material and manufacturing method.

Conclusion

Information provided in this application demonstrates that Blue Sky Bio Aligner G & Blue Sky Plan Software for Blue Sky Bio Aligner G & Blue Sky Plan Software for Blue Sky Bio Aligner G are substantially equivalent to the predicate devices. Blue Sky Bio Aligner G & Blue Sky Plan Software for Blue Sky Bio Aligner G share the same indications for use, similar material composition, similar physical properties and technological characteristics as the predicate devices.