April 3, 2024

Blue Sky Bio, LLC
% Patsy Trisler
Regulatory Consultant
Trisler Consulting, dba
306 Turnberry Court
Lebanon, Indiana 46052

Re: K232653
Trade/Device Name: Blue Sky Plan Software, Blue Sky Bio Aligner Z, and Blue Sky Bio Aligner Z FLX
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC, PNN
Dated: August 30, 2023
Received: March 6, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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)*

K232653

Device Name

Blue Sky Plan Software, and Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX

Indications for Use *(Describe)*

Blue Sky Plan Software orthodontic module 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 and aligners, 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 treatment, and at the end of treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX are 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 force.

The use of the Blue Sky Plan Software module 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)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

K232653

Submitter Name: Blue Sky Bio, LLC

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Libertyville, IL 60048

Email Address: Azickmann@blueskybio.com

Contact Person: Dr. Albert Zickmann, VP, Product Development

Date Prepared: March 6, 2024

Device Trade Name: Blue Sky Plan Software and Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX

Device Names	Orthodontic Software	Sequential Aligner
Regulation Numbers	21 CFR 872.5470	21 CFR 872.5470
Product Codes	PNN	NXC
Class	2	2

Predicate Device Information	**Predicate #1 (Primary):**	**Predicate #2 (Secondary)**:
510(k) #, Device Trade name & Manufacturer	K223518 iOrtho, Shanghai EA Medical Instruments Co., Ltd.	K192596, uLab Systems Dental Aligner Kit; uLab Systems, Inc.
Device Name	Orthodontic Software	Aligner, Sequential
Regulation Number	21 CFR 872.5470	21 CFR 872.5470
Product Code	PNN	NXC

Reference Devices		
510(k) #, Device Trade name & Manufacturer	K180107 Blue Sky Bio Aligner; Blue Sky Bio LLC	K221845, Blue Sky Bio Aligner G & Blue Sky Plan Software for Blue Sky Bio Aligner G; Blue Sky Bio, LLC
Device Name	Aligner, Sequential	Orthodontic Software
Regulation Number	21 CFR 872.5470	21 CFR 872.5470
Product Code	NXC	PNN, NXC

Indications for Use: Blue Sky Plan Software orthodontic module 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 and aligners, 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 treatment, and at the end of treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX are 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 force.

The use of the Blue Sky Plan Software 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.

Device Description: Summary of Technological Characteristics, Material Composition and Mechanism of Action

A dental clinician, using a standard personal computer prescribes the orthodontic appliance based on an assessment of the patient's teeth and determines the course of treatment using the Blue Sky Plan Software. 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 the aligners. Alternatively, the dental clinician may generate the digital files by scanning the patient's mouth directly, using an intraoral scanner, and then send the files to the dental lab.

The Blue Sky Bio Aligners (Z and Z FLX) consist of a series of clear plastic aligner trays which are fabricated with the selected thermoplastic material (either a thin polyurethane sheet or a composite of copolyester and polyurethane). Both materials are commercially used for thermoforming customized removable aligners for the intended use.

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 Z or Z FLX.

The finished aligners are sent to the dental clinician who then provides them to the patient, confirming fit and form. Over a period of time, additional aligner trays are provided sequentially to the patient by the clinician to gradually move the target teeth to the designed position. The dental clinician monitors treatment from delivery of the first aligner to the final aligner.

The trays are held in place by pressure and can be removed by the patient at any time.

Device Testing

<u>Laboratory Testing</u>

Test data were submitted to validate the processes used for the design and manufacture of the clear customized aligners.

Testing was conducted to characterize device performance characteristics according to ASTM D638.

Testing to verify and validate the software has been included in this 510(k) documentation.

Biocompatibility

ISO 10993 testing, according to Good Laboratory Practices, has been performed to assure the two thermoplastic materials are biocompatible and non-toxic for the oral contact use:

Part 3 (Bacterial Mutagenicity – Ames Assay)
Part 5 (Cytotoxicity Elution - MEM),
Part 10 (Intracutaneous/Intradermal) Reactivity),
Part 10 (Oral Mucosa Irritation)

Animal | Human Testing

No animal or human testing are required for this product.

Comparison to Predicate and Reference Devices:

The similarities in intended use and technological characteristics comparing the subject Blue Sky Plan Software and Blue Sky Bio Z and Z FLX aligners to the Predicates follow:

- The software has the same intended use as the Primary Predicate and functions similarly as noted.
- The aligners are clear plastic, customized sequential aligners with the same intended use and mechanism of action as the Secondary Predicate and Reference K180107:
  - They are intended for realignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle force.
  - They use the same thermoplastic materials as the Secondary Predicate.
  - They are thermoformed using similar processes as the Secondary Predicate and using the same processes as the Reference Device (K180107).

The subject device software and the Primary Predicate software have proprietary differences, but they have the same intended use and function equivalently. Furthermore, both Reference devices use the same software.

The only differences between the subject device aligners and the Secondary Predicate are the minor proprietary differences in the processes; those processes are standard in this field for thermoforming/manufacturing clear aligners. Furthermore they are the same processes used for Reference aligner K180107.

Details follow on the Substantial Equivalence Comparison Tables (Table A for the PNN code; and Table B for NXC code).

Substantial Equivalence Conclusion:

Based on the documentation presented in the 510(k), as summarized herein, it can be concluded that these clear aligner systems are substantially equivalent to the Predicate devices.

Substantial Equivalence Comparison Tables

Table A – Comparison of Orthodontic Software

Trade Name:	**Subject Device:** **Blue Sky Plan Software, & Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX**	**Primary Predicate:** **iOrtho**	**Comparison to Predicate**
510(k) #	K232653	K223518	n/a
Manufacturer	Blue Sky Bio, LLC	Shanghai EA Medical Instruments Co., Ltd.	n/a
Device Name 21 CFR Product Code Class	Orthodontic Software & Sequential Aligner 872.5470 PNN & NXC 2	Orthodontic Software 872.5470 PNN 2	Same
Intended Use	Blue Sky Plan Software orthodontic module 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 and aligners, 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 treatment, and at the end of treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX are 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 force.	iOrtho is intended for use as a medical front-end device providing tools for management of orthodontic cases, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media, Sequential aligners) 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. The use of iOrtho 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.	Same software Intended Use as the Primary Predicate

	The use of the Blue Sky Plan Software module 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.		
Supported Anatomic Area	Maxilla/Mandible	Maxilla/Mandible	SE
Mechanism of Action	Medical front-end software as described in Intended Use statement	Medical front-end software as described in Intended Use statement	SE.
Software Characteristics	• Manages patient & case base data • Collects study material • Segments study material • Aligns study material • Measures study material • Measures point selection • Analyzes study material • Prepares treatment simulations and options • Designs virtual appliances • Surface scans for intraoral scanners • Surface scans from STL files	• Manages patient & case base data • Collects study material • Segments study material • Aligns study material • Measures study material • Measures point selection • Analyzes study material • Prepares treatment simulations and options • Designs virtual appliances • Surface scans for intraoral scanners • Surface scans from STL files	SE
Rx or OTC	Rx only	Rx only	SE

Table B: Comparison of Sequential Aligners

Trade Name:	**Subject Device: Blue Sky Plan Software, & Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX**	**Secondary Predicate: uLab Systems Dental Aligner Kit**	**Comparison to Predicate**
510(k) #	K232653	K192596	n/a
Manufacturer	Blue Sky Bio, LLC	uLab Systems, Inc.	n/a
Device Name 21 CFR Product Code Class	Sequential Aligner & Orthodontic Software 872.5470 PNN & NXC 2	Sequential Aligner 872.5470 NXC 2	Same
Intended Use	Same as Table A above	The uLab Systems Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.	Same aligner Intended Use as both Predicates.
Mechanism of Action of Sequential Aligner Trays	Orthodontic tooth movements through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on doctor's prescription.	Orthodontic tooth movements through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on doctor's prescription.	SE
Treatment planning	Use of orthodontic software program	Use of orthodontic software program	SE
Method of Use	Each customized aligner is worn as prescribed for 20-22 hours per day	Each customized aligner is worn as prescribed for 20-22 hours per day	SE
Material and Form	Sheet of thin thermoformed polyurethane or copolyester and polyurethane composite	Sheet of thin thermoformed polyurethane or copolyester and polyurethane composite	SE to Secondary Predicate
Biocompatibility	Materials shown to be biocompatible and non-toxic.	Materials shown to be biocompatible and non-toxic.	SE to Secondary Predicate
Rx or OTC	Rx only	Rx only	SE