December 19, 2024

Cristaline Aligners GmbH
℅ Patsy Trisler
Regulatory Consultant
Trisler Consulting (dba)
306 Turnberry Court
Lebanon, Indiana 46052

Re: K242892
Trade/Device Name: Cristaline Aligners Z FLX
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 18, 2024
Received: September 23, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242892

Device Name

Cristaline Aligners Z FLX

Indications for Use *(Describe)*

Cristaline Aligners A FLX are series of clear, lightweight, plastic appliances, indicated for 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.

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.

SUBMITTER Name:	Cristaline Aligners GmbH
Address:	Hanauer Strasse 1-5 75181 Pforzheim, Germany
Contact Person: **Email:**	Dr. Boris Simnovski dr.simanovoski@gmail.com
Date Prepared:	November 13, 2024
DEVICE Trade Name:	Cristaline Aligners Z FLX
Common Name:	Aligner, Sequential (Clear Braces)
Classification Name **Number** **Product Code** **Regulatory Class**	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Review Panel	Dental
PRIMARY PREDICATE:	K232653, Blue Sky Plan Software, Blue Sky Bio Aligner Z and Blue Sky Bio Z FLX; Blue Sky Bio, LLC
DEVICE DESCRIPTION	Cristaline Aligners Z FLX are comprised of a series of clear, thin, thermoformed removable aligner trays that are designed to correct tooth malocclusions without the use of conventional wire and bracket orthodontic technology. They are manufactured using a biocompatible thermoplastic sheet composed of a composite of co-polyester and polyurethane. They are provided non-sterile and are customized for each patient according to the dental clinician's prescription. The dental health professional (dentist/orthodontist) provides a digital file (scan) of the patient's teeth to Cristaline. Based on the dental health professional's treatment plan, Cristaline develops a digital plan using commercially available treatment planning software. Upon approval by the dental health professional, molds are created with 3D-printing technology and the clear aligners are formed on the molds. The finished, customized aligners are provided to the dental health care professional who provides them to the patient, confirming fit and design.
MECHANISM OF ACTION	Each aligner in the set is used for the specified period of time, usually 1-2 weeks, to exert gentle force to achieve progressive realignment of the teeth until the final correction has been achieved. The daily treatment time is approximately 22 hours, or except during eating, based on the clinician's prescribed treatment plan. The aligner trays are held in place by pressure and can be removed by the patients at any time.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The thermoplastic materials used for the manufacture of the aligners are identical to the material used for making the Predicate device aligner Z FLX. The treatment planning software system used is the Predicate Blue Sky Plan software.

INDICATIONS FOR USE STATEMENT	Cristaline Aligners Z FLX are series of clear, lightweight, plastic appliances, indicated for 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.
SAFETY TESTING	Testing of the aligner material has been conducted according to ISO 10993, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system*, was performed by a GLP-certified contract research laboratory: • In vitro Cytotoxicity (Part 5) • Oral Mucosal Irritation (Part 10) • Skin Sensitization (Part 10)
OTHER TESTING	Bench testing was performed to validate the manufacturing process to ensure the accuracy of the final aligners compared to the initial digital scans. Final reports of the testing of aligners fabricated with the thermoplastic material was part of the 510(k) package. In vivo Animal and Human Clinical performance testing are not required for this device category.
COMPARISON TO THE PREDICATE DEVICE	The Cristaline Aligners Z FLX devices have the same intended use as the predicate device. The thermoplastic polymer materials are the same as the Predicate and digital treatment planning involves use of the Predicate's commercially available software The processes for fabrication of the clear aligners, while proprietary to each manufacturer, makes use of similar, industry-standard processes using similar machines. Any differences in the specific manufacturing processes do not raise new questions of safety and effectiveness.
SUBSTANTIAL EQUIVALENCE CONCLUSION	The information and data provided in this 510(k) establish that the Cristaline Aligners Z FLX devices are substantially equivalent to the Predicate Blue Sky Bio device in the intended use, design, principle of operation, technology (same treatment planning software as the Predicate), and thermoplastic material (same as aligner Z FLX of the Predicate device). See the following SE Comparison table.

Substantial Equivalence Comparison Table

510(k) Number	Proposed Device K242892	Predicate #1 K232653	SE Comparison
Device Name	Cristaline Aligners Z FLX	Blue Sky Plan Software, Blue Sky Bio Aligner Z and Blue Sky Bio Z FLX	N/A
Manufacturer	Cristaline Aligners GmbH	Blue Sky Bio, LLC	N/A
Classification Regulation and Name Product Code Class	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	Same
Indications for Use	Cristaline Aligners Z FLX are series of clear, lightweight, plastic appliances, indicated for 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.	Blue Sky Bio Aligner Z and Blue Sky Bio Aligner Z FLX are series of clear, lightweight, plastic appliances, indicated for 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.	Same for the Z FLX Aligner.
Mode of Action	The removable appliance applies continuous gentle forces on teeth according to the plan prescribed by the doctor.	The removable appliance applies continuous gentle forces on teeth according to the plan prescribed by the doctor.	No differences
Description of Use	Each removable preformed plastic tray, prescribed by the Dr, is worn by the patient usually for 1-2 weeks, prior to using the next sequential aligner tray according to Dr's direction.	Each removable preformed plastic tray, prescribed by the Dr, is worn by the patient usually for a couple weeks, prior to using the next sequential aligner tray according to Dr's direction.	No differences
Material	Thermoplastic co-polyester polyurethane composite.	For Z FLX aligner: thermoplastic co-polyester polyurethane composite	No differences
Manufacturing Process	Forming of plastic sheets on SD printed dental models designed with use of the treatment planning software	Forming of plastic sheets on SD printed dental models designed with use of the treatment planning software	Manufacturing processes used are standard in the field and similar to predicate's.
Software	Commercially available treatment planning software is used – same as Predicate	Included in 510(k)	Same software is used
Prescription Use	Rx	Rx	Both are Rx
Biocompatibility	Testing to meet requirements for Category C	Testing to meet requirements for Category C	Relied on the same testing performed by thermoplastic material manufacturer.

Process Validation	Validation to determine fit and form of manufactured aligners.	Validation to determine fit and form of manufactured aligners.	Similar testing performed.