February 22, 2024

TNS Co., Ltd.
Won-Gun Chang
CEO
908, 46, Digital-ro 9gil
Geumcheon-gu, Seoul 08512
SOUTH KOREA

Re: K232074
Trade/Device Name: Serafin®
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 23, 2023
Received: November 24, 2023

Dear Won-Gun Chang:

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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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)*
K232074

Device Name
Serafin®

Indications for Use *(Describe)*
The Serafin is intended for the orthodontic treatment of malocclusion

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Date: February 21, 2024

1. SUBMITTER

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2. DEVICE

·Trade Name: Serafin®
·Common Name: Clear Aligner System
·Regulation Number 872.5470
·Class: 2
·Classification Product Code: NXC
·Classification Name: Orthodontic plastic bracket

3. PREDICATE DEVICE

Serafin®
: K220287 (Primary predicate) Invisalign, Align Technology Inc.

4. DEVICE DESCRIPTION

Serafin® is composed of series of transparent removable orthodontic appliances manufactured using thermoforming technology based on a 3D model of the patient's teeth, customized according to a Dental Practitioner's specific prescription, indicated for treatment of dental malocclusion by applying continuous gentle force to realign teeth.

The time for each stage of aligner usage is set in the personal treatment plan, and this varies for each patient and the Dental Practitioner's choice. Each set of aligners needs to be worn for at least 2 weeks. Patients the total treatment time lasts about 6 to 24 months.

5. INDICATIONS FOR USE

Serafin®

• The Serafin is intended for the orthodontic treatment of malocclusion.

6. NON-CLINICAL TESTING

The following test articles were tested based on the referenced standard. All the test results met the preset test criteria.

1) Physical and chemical test

- Guideline on Review and Approval for appliance, Orthodontic, Resin (Sheet Type)(2018.12.) (MFDS)

  – Appearance, Dimension, Water sorption & solubility, 3-point flexural strength, hardness

  – Appearance, pH, Potassium permanganate reducing substances residue, Residue on evaporation, Heavy metals, Ultraviolet-visible spectrum
- ISO 20795-2 Dentistry – Base polymers – Part 2: Orthodontic base polymers

2) Biological evaluation

- ISO 10993-1 – Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 7405 – Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-17 – Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18 – Biological evaluation of medical devices - Part 18: Chemical characterization
- ISO 10993-5 – Biological evaluation of medical devices - Part 5: Cytotoxicity
- ISO 10993-10 - Biological evaluation of medical devices - Part 10: Skin sensitization, Acute oral mucosa irritation, Intracutaneous reactivity
- ISO 10993-11 - Biological evaluation of medical devices - Part 11: Acute systemic toxicity
- ISO 10993-23 - Biological evaluation of medical devices - Part 23: Tests for

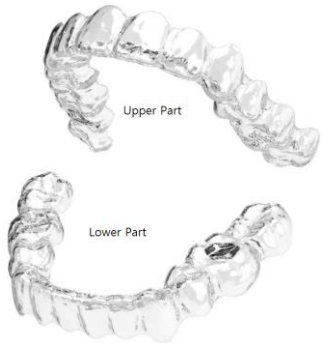
irritation

- ADA ANSI 41-2020 Evaluation of Biocompatibility of Medical Devices Used in Dentistry

7. SUBSTANITAL EQUIVALENCE

	Subject device	Predicate Device	Discuss/Justify the Differences
510(k) Number	K232074	K220287	-
Trade Name	Serafin®	Invisalign	-
Manufacturer	TNS Co., Ltd.	Align Technology Inc.	-
Common Name	Clear Aligner System	Aligner, Sequential	Same
Device Class	2	2	Same
Product Code	NXC	NXC	Same
Device Description	Serafin® is composed of series of transparent removable orthodontic appliances manufactured using thermoforming technology based on a 3D model of the patient's teeth, customized according to a Dental Practitioner's specific prescription, indicated for treatment of dental malocclusion by applying continuous gentle force to realign teeth. The time for each stage of aligner usage is set in the personal treatment plan, and this varies for each patient and the Dental Practitioner's choice. Each set of aligners needs to be	Invisalign is series of transparent removable orthodontic appliance, indicated for treatment of dental malocclusion. Invisalign consists of an upper and lower parts in variable sizes and lengths customized for a patient. It is produced by using 3D printer based on 3D scanned image file sent by a Dental Practitioner. The aligners and attachment templates are made of thermoplastic polymer, with/without PFA system made of photopolymerizable methacrylate based resin.	Equivalent

	worn for at least 2 weeks. Patients the total treatment time lasts about 6 to 24 months.		
Indications for use	The Serafin is intended for the orthodontic treatment of malocclusion.	The Invisalign System is intended for the orthodontic treatment of malocclusion.	Same
Clinical condition	Overbite, underbite, crossbite, gap teeth, open bite, crowded teeth, baby and permanent teeth. Limitations include severe cases where large movement of a tooth is necessary such as a tooth rotated over 20 degrees, large gap between teeth, teeth which require intrusion or extrusion	Overbite, underbite, crossbite, gap teeth, open bite, crowded teeth, baby and permanent teeth. Limitations include severe cases where large movement of a tooth is necessary such as a tooth rotated over 20 degrees, large gap between teeth, teeth which require intrusion or extrusion	Same
Patient Population	**Child and adolescent(when full permanent dentition is present), Adults**	Children, Adolescents and Adults	Same
Use Location	Dental intraoral Devices	Dental intraoral Devices	Same
OTC or Prescription (Rx) Device	Rx only	Rx only	Same
Design			
Principle of Operation	Serafin® is series of transparent removable orthodontic appliances, indicated for treatment of dental malocclusion. It is produced by using 3D printer based on 3D scanned image file sent by a Dental Practitioner along with a prescription of a specific patient. Series of clear plastic appliances (Aligners) moves	The Invisalign System consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) and proprietary 3-D software. The aligners gently move the patient's teeth in small increments from their original state to a more optimal, treated state.	Equivalent

	the patients' teeth in small increments from their original state to a final, treated state by applying continuous gentle force to teeth while the patient is wearing it.		
Appearance			Equivalent
3D Software	3D Software: Produces 3D model file of the the digital scan. Create a treatment plan which is reviewed by dental practitioner to reject or request modifications. Approved treatment plan model is 3D printed.	3D Software: Produces 3D model file of the PVS impression or the digital scan. Create a treatment plan which is reviewed by dental practitioner to reject or request modifications. Approved treatment plan model is 3D printed.	Equivalent
Materials	Thermoplastic polymer : Zendura FLX : Thermoplastic Urethane, Copolyester (3-layer structure)	Thermoplastic polymer SmartTrack™ (Multilayer structure)	Equivalent
Physical State	Transparent removable orthodontic appliances consist of an upper and lower parts	Transparent removable orthodontic appliances consist of an upper and lower parts	Same
Material property	Zendura FLX Demonstrates sufficient Ultimate Flexural Strength, Water Sorption, Water Solubility as per ISO 20795-2 : 2013.	SmartTrack™ is material engineered for use with Invisalign orthodontic	Equivalent

	Intended, marketed to be used as dental aligner	treatment (Polyurethane) Intended to be used as dental aligner	
Manufacturing process	Thermoforming on models, Trimming, Marking	Thermoforming on models, Trimming, Marking	Same
Biological			
Tissue Contact	Surface device, permanent use (>30 days), Mucosal membrane	Surface device, permanent use (>30 days), Mucosal membrane	Same
Anatomical site	Intact teeth, gingival mucosa, interior vermilion (inner lip), and tongue	Intact teeth, gingival mucosa, interior vermilion (inner lip), and tongue	Same
Contact duration	at least 20 hrs or longer a day, up to 30 days	at least 20 hrs or longer a day, up to 30 days	Same
Biocompatiblility	Biological risk assessment, Toxicological risk assessment as per ISO 10993-1, ISO 7405	Biocompatibility per the ISO 10993 series standards	Equivalent

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject devices share the same indications for use and the principle of operation as the predicate devices. They are intended for the same clinical conditions, patient populations, and use locations.

Predicate device includes an optional mandibular advancement feature (MAF), but subject device does not provide a MAF feature. The MAF option is a necessary function for ‘Skeletal malocclusion’, so it does not correspond to the indications for subject device.

Both devices comprise a series of transparent, removable orthodontic appliances, used for at least 20 hours a day over a period of several weeks. The manufacturing process begins with a 3D image file of a patient's dentition, which serves as an input to each manufacturer's software. Each software identifies the individual teeth requiring treatment. The software then generates a 3D model of the patient's dentition, incrementally modifying it towards alignment. This 3D model is then printed out using a 3D printer. Subsequently, a thermoplastic polyurethane material is heated and moulded onto the 3D printed model, known as a thermoforming process. Any excess material is eliminated by trimming process. The resulting plastic appliances, both for Serafin® and Invisalign, are designed to apply a gentle, continuous force on the malocclusion site to realign the teeth.

Correspondingly, the principles of operation, intended use, manufacturing process, and 3D modeling process for Serafin® and Invisalign are identical. Both devices utilize a similar thermoforming polymer as a material, which demonstrates chemical, biological, and functional equivalence. The materials are thermoplastic polymers with a biocompatible polyurethane copolymer and are intended for use as clear aligner material.

However, since the materials are not exactly the same, further biological assessments and pre-clinical performance tests have been carried. For biocompatibility, Serafin® was tested as per ISO 10993-1 in Biological Risk Assessment. In addition, Toxicological Risk Assessment was conducted to monitor and mitigate the biological risk from unintended process residuals and degradation material under the light-curing process in 3D printing and the thermoforming process.

Regarding physical properties and clinical performance, Zendura FLX was tested according to "ISO 20795-2 Dentistry - Base polymers - Part 2: Orthodontic base polymers," under a 37°C wet environment. Since orthodontic base polymers are categorized as Type 3 (thermoplastic materials), testing was conducted for Flexural Modulus, Flexural Strength, Tear Strength, Water Sorption, and Water Solubility. The Flexural Modulus did not meet standard requirement of 1500 MPa. However, this requirement is relevant to highly rigid or inflexible materials, which does not reflect the

current requirements for thermoplastic aligners. Considering that Serafin® and Invisalign are engineered to apply a subtle force for realignment, this standard does not apply, and the value primarily serves as an informative detail about the device's physical properties. The other results conformed to the standard, indicating good toughness, an effective ability to move teeth, low water uptake, and low water solubility.

Consequently, it can be concluded that the subject devices are substantially equivalent to the predicate devices in terms of similarity, risk acceptability, and efficacy.