June 19, 2019

Five Star Orthodontic Lab & Supply
Andrew Loch
Sales Manager
2928 Metro Street, Suite 102
Denton, Texas 76207

Re: K182658
Trade/Device Name: Bioliner™
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 14, 2019
Received: May 17, 2019

Dear Andrew Loch:

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental 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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182658

Device Name
Bioliner™

Indications for Use *(Describe)*

The Bioliner™ is an aligner system indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and 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.

510(k) Summary

Submitter: Five Star Orthodontic Lab & Supply, Inc.
2928 Metro Street. Suite 102
Denton, TX 76207

Contact Person: Andrew Loch
Sales Manager
Phone: (800) 521-2351
andrew@fivestarortho.com

Submission Date: June 17, 2019

Trade Name: Bioliner™

Common Name: Aligner, Sequential

Classification Name: Orthodontic Plastic Bracket; 21 CFR 872.5470; NXC

Device Classification: Class II

Predicate Device: K173785, Derby Dental Laboratory Custom Clear Aligner System

Reference Devices: K062828, Dentsply Intl, Inc. Mouthguard and Aligner Materials

K152086, 3Shape A/S 3Shape Ortho System

Description of Device:

The Bioliner™ aligner system is used for treatment of misalignment and malocclusion of permanent teeth by use of clear plastic aligners. The Bioliner™ aligner system is a sequential set of removable aligners prescribed by a dentist that are custom made for a specific patient.

Each Bioliner™ sequential aligner introduces subtle changes in the position of the teeth from the previous aligner. Each Bioliner™ is fabricated from 1.0mm thermoplastic. For each patient, the Bioliner™ will be designed by a Five Star Orthodontic Laboratory & Supply, Inc. technician utilizing 3Shape (K152086) orthodontic validated software and tooth movement recommendations from the prescribing dentist. Once fabricated, the Bioliner™ aligners are provided to the dentist, and over a period of time, the dentist provides the next sequential aligner to the patient in order to move the teeth to the desired final position.

The aligners are removable at any time and treatment may be discontinued at any time. The Bioliner™ aligners are a non-sterile, single use device.

Intended Use / Indications:

The Bioliner™ is an aligner system indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

Predicate Device Comparison:

Property or Characteristic	Proposed Device Five Star Orthodontic Laboratory & Supply, Inc. Bioliner™	Predicate Device Derby Dental Laboratory Custom Clear Aligner System (K173785)
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC
Classification	II	II
Indications for Use	The Bioliner™ is an aligner system indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	The Custom Clear Aligner System is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.
Prescription or OTC	Prescription	Prescription
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.
Number of aligner sets to complete treatment	Patient specific – determined during design of aligners utilizing orthodontic software	Patient specific – determined during design of aligners utilizing orthodontic software
Material	Essix Ace Plastic (K062828)	Thin thermoformed polyurethane
Sizes	Patient specific	Patient specific
Body Location	Mouth	Mouth
Manufacturing Process	Thermoformed	Thermoformed
Software Used during manufacturing	Use of 3Shape Ortho System (K152086)	Use of 3Shape Ortho System (K152086)
Provided Non-Sterile	Yes	Yes

The Bioliner™ aligners are manufactured from Essix Ace Plastic (K062828), whereas the predicate device is manufactured from polyurethane. Polyurethane is a more flexible material as compared to the thermoplastic material that the Bioliner™ aligners are manufactured from. The thermoplastic material (Essix Ace Plastic) used for the Bioliner™ aligners has been cleared for orthodontic use in

K062828 and the material labeling specifically indicates use of the material for aligners.

A biocompatibility risk assessment has been completed for the Bioliner™ aligners taking into account not only the material used for fabrication, but also the manufacturing processes utilized during fabrication. As identified below, all applicable biocompatibility testing has been performed on the Bioliner™ aligners.

Summary of Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Bioliner™ to the predicate device.

Summary of Non-Clinical Testing:

Biocompatibility testing was performed for the Bioliner™ aligners in accordance with ISO 10993-1 and its applicable parts. The mechanical properties of the Essix Ace plastic (K062828) has been previously demonstrated by the manufacturer as appropriate for use with aligners, therefore no additional testing was required. There is sufficient data to demonstrate substantial equivalence to the predicate device.

The Bioliner™ aligners are manufactured using 3Shape orthodontic software (K152086). Software validation by Five Star Orthodontic Laboratory and Supply was not required since 3Shape has received 510(k) clearance and has been validated by the manufacturer.

A manufacturing validation was performed to ensure the dimensional accuracy of the Bioliner™ aligners through the manufacturing process. This validation demonstrated that the finished Bioliner™ aligners match the software output specifications.

Conclusion:

Based upon the information presented in this submission, it is concluded that the Bioliner™ system is substantially equivalent to the predicate device in regard to indications for use, design and technology.