December 22, 2020

3D Diagnostix Inc.
Ehab Amin
Quality and Regulatory Consultant
24 Denby Road
Allston, Massachusetts 02134

Re: K200908
Trade/Device Name: iSMILE
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 27, 2020
Received: November 27, 2020

Dear Ehab Amin:

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, M.ChE.
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: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K200908

Device Name

iSMILE

Indications for Use *(Describe)*

iSMILE is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

3D Diagnostix Inc.'s iSMILE

510K Number: K200908

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

[COMPANY'S NAME AND ADDRESS]

3D Diagnostix Inc

24 Denby Road

Allston, MA 02134

USA

Phone: 1-617-820-5279

Fax: 1-617-904-1853

Contact Person: Ehab Mahmoud

Date Prepared: November 23, 2020

Name of Device and Name/Address of Sponsor

Name of Device:	iSMILE
Common or Usual Name:	Dental Plastic Aligners
Classification Name:	Orthodontic Plastic Brackets – Sequential Aligners (21 CFR 892.5470)
Regulatory Class:	II
Product Code:	NXC

Primary Predicate Devices

Invisalign System	K081960	Align Technology, Inc.

Intended Use / Indications for Use

The i5MILE is indicated for use in alignment of teeth during orthodontic treatment of malocclusion.

Technological Characteristics

The **iSMILE** Aligners that are produced have the same technological characteristics as the primary predicate device, in that all the devices are made from commercially available plastic that is thermoformed to create a customized, patient-specific aligner. The aligners are then used for minor tooth movement by way of continuous gentle force.

In both devices, the aligners are created by thermoforming commercially available plastic material. The **iSMILE** Aligners are thermoformed by **3D Diagnostix Inc.** and in the case of the primary predicate device; the aligners are thermoformed by an outside laboratory.

The **iSMILE** Aligner incorporates the use of attachments to create spaces and force points in order to cause minor tooth movement. These force points are located in specific areas and positioned in such a way that they provide a continuous force which slowly dissipates over time on the tooth to be moved for as long as the aligner is worn.

Performance Data

As part of demonstrating substantial equivalence of **iSMILE** to the primary predicate device that are subject to this 510(k) submission, **3D Diagnostix Inc.** completed a number of non-clinical performance tests. **iSMILE** meets all the requirements for overall design, biocompatibility, and performance results confirming that the design output meets the design inputs and specifications for the device.

iSMILE passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1 passed cytotoxicity, sensitization, irritation, Acute Systemic Toxicity, Mutagenicity, and Subacute Toxicity for the used thermoforming sheets.
- There is no defined specification or standard for tensile strength so a sample of base materials used for fabrication of aligners were tested and analyzed producing acceptable results for tensile strength yield.

- There is no defined specification or standard for aligner elongation which a sample of based materials used for fabrication of aligners were tested and analyzed showing acceptable results in comparison of break point.

- There is no defined specification or standard for tensile stress so a sample of base materials used for fabrication of aligners were tested and analyzed producing acceptable results for tensile stress at break point.

- There is no defined specification or standard for modulus so this was tested for the base materials used for fabrication of aligners to show acceptable results between the samples tested.

- There is no defined specification or standard for load of materials which found acceptable results when tested and analyzed for samples of base material tested used for fabrication of aligners.

- There is no defined specification or standard for water absorption which found acceptable results when tested and analyzed for fabricated aligners.

- Process Flow validation was performed to ensure that the finished device matches the software output specifications. The output and work model and aligner were tested and compared. Aligners met the acceptance criteria of this testing.

In all instances, the **iSMILE** functioned as intended and **Biocompatibility Testing, and Process Flow Validation** observed was as expected.

Substantial Equivalence

Feature	Proposed Device iSMILE	Primary Predicate Device Invisalign System
K Number	**K200908**	**K081960**
Manufacturer	3D Diganostix Inc.	Align Technology, Inc.
Regulation Number	21 CFR 872.5470	21 CFR 872.5470
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC
Device Class	Class II	Class II
Indications for Use	iSMILE is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.
Device Description	The iSMILE is a sequence of transparent aligners created from a digital orthodontic treatment plan. The iSMILE aligner is fabricated of a transparent thermoformed polyurethane plastic. Each aligner delivery a unique combination of minor forces to create the planned tooth movement. The digital orthodontic treatment plan is created by a dental health professional. The **iSMILE** Aligner incorporates the use of attachments to create spaces and force points in order to cause minor tooth movement. These force points are located in specific areas and positioned in such a way that	The current Invisalign system is a series of clear plastic aligners that are used to replace traditional orthodontic wires and brackets for the alignment of malocclusion or misaligned teeth. This series of aligners moves the teeth gently, and in small increments, from their original to their final treated position for improved dental alignment.

Feature	Proposed Device iSMILE	Primary Predicate Device Invisalign System
K Number	**K200908**	**K081960**
	they provide a continuous force which slowly dissipates over time on the tooth to be moved for as long as the aligner is worn.	
Mode of Action	Orthodontic tooth movement occurs 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 occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription
Anatomy Location	Mouth; mucosal	Mouth; mucosal
Size	Patient specific	Patient specific
Manufacturing Method	Thermoforming	Thermoforming
Material	Thermoplastic Polymer	Thermoplastic Polymer
Material Properties	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.
Software Used for Ordering Workflow	Yes	Yes

3D Diagnostix .COM	**3D Diagnostix Inc.**
	iSMILE Dental Aligners 510K Additional Information

Feature	Proposed Device iSMILE	Primary Predicate Device Invisalign System
K Number	**K200908**	**K081960**
Design		

iSMILE has the same intended uses and similar indications, technological characteristics, Manufacturing Method, Material Used and principles of operation as its primary predicate device. **iSMILE** is substantial equivalent to the **Invisalign System**.

There are no differences between **iSMILE** and **Invisalign System** was defined therefore a performance testing was performed to **iSMILE** to ensure that patients are receiving the aligners as prescribed by the practitioner to move their teeth as intended (final position). The results of this performance testing are accepted according to acceptance criteria and do not raise any additional concerns.

Conclusions

iSMILE Aligners moves teeth by way of continuous gentle force through a sequence of clear aligners that follow the treatment plan developed by the clinician as does the primary predicate device, **Invisalign System**.

The conclusions drawn from the data included in this submission, demonstrates that the **iSMILE** Aligner is substantially equivalent to the primary predicate devices cleared under premarket notification **K081960 (Primary Predicate Device)** in indications for use, design, technological characteristics, mechanism of action, performance, materials and biocompatibility.