November 12, 2021

SprintRay Inc
Sara Moghtadernejad
Quality Assurance Speciality
2705 Media Center Drive, Suite 100A
Los Angeles, California 90065

Re: K212448
Trade/Device Name: NightGuard Flex
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: September 9, 2021
Received: September 10, 2021

Dear Sara Moghtadernejad:

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 and
ENT 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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K212448

Device Name

NightGuard Flex

Indications for Use *(Describe)*

The SprintRay NightGuard Flex is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.

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.

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VII. 510(K) SUMMARY K212448

The Company’s 510(k) Summary is provided on the following pages.

510(k) SUMMARY

SprintRay's NightGuard Flex

Submitter: SprintRay Inc.
2705 Media Center Drive, Suite 100A
Los Angeles, CA 90065

Phone: (800) 914-8004

Contact Person: Sara Moghtadernejad

Date Prepared: July 05, 2021

Name of Device: NightGuard Flex

Common or Usual Name: MouthGuard, Prescription

Classification Name: MouthGuard, Prescription

Regulatory Class: Unclassified

Product Code: MQC, KMY

Predicate Device

KeySprint's KeySplint Soft (K183598)

Reference Device

EnvisonTech's E-Guard (201173)

Device Description

The NightGuard Flex consists of a curable dental acrylate resin that is manufactured in a dental office based on a 3D scanned image of a patient's teeth. The acrylate resin material is designed to be used in conjunction with a scanned 3D image, and 3D printer assembly, to locally manufacture out a dental appliance based on the clinician's judgment of patient need.

NightGuard Flex is designed to meet appropriate ISO standards for flexibility, sorption and tensile strength to withstand prolonged use in the oral cavity. It is delivered non-sterile and instructions are provided on cleaning the material prior to providing it to a patient. Curing is performed with a UV lamp. The appliance is

then cleaned, trimmed and verified to fit in the dental office before the patient leaves.

Intended Use / Indications for Use

The NightGuard Flex is intended to be used for the manufacture of orthodontic and dental appliances in a clinical setting by trained dental professionals.

The NightGuard Flex is indicated for use in the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.

Summary of Technological Characteristics

Light-based curing of a 3D printed acrylate resin is the technological principle for both the subject and predicate devices. The NightGuard Flex is poured into a 3D printer, which relies on scanned images of the patient's oral cavity to produce a dental appliance. At a high level, the subject and predicate devices are based on the following same technological elements:

- Are a pourable acrylate resin
- Are used in conjunction with 3D printers, which rely on common 3D images to define the fabricated dental appliance
- Are cured prior to final trimming and cleaning
- Are used for the fabrication of orthodontic and dental appliances

The following technological differences exist between the subject and predicate devices:

- Differences in acrylate resin material

Performance Data

Biocompatibility testing was performed on samples of the NightGuard Flex that had been formed into dental appliances using a 3D printer.

Additional bench testing based on the test steps laid out in ISO 20795-1 and -2 was performed using dental appliance fabricated from NightGuard Flex. This includes testing to demonstrate that finished NightGuard Flex appliances meet predefined acceptance criteria for tensile strength, flex strength, impact and hardness characteristics, as well as water sorption and solubility, and the presence of residual methyl-methacrylate monomers.

In all instances, the NightGuard Flex functioned as intended and the outcomes were as expected.

Conclusions

The NightGuard Flex is as safe and effective as its predicate device. The NightGuard Flex has the same intended use and indication, and similar technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NightGuard Flex and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NightGuard Flex is as safe and effective as the predicate device. Thus, the NightGuard Flex is substantially equivalent.