September 17, 2019

Crane Dental Laboratory, Inc
Kevin Crane
President
3515 Buffalo Road, Suite 30
Rochester, NY 14624

Re: K181416
Trade/Device Name: Sapphire Dorsal Comfort Fit
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK
Dated: June 18, 2019
Received: June 19, 2019

Dear Kevin Crane:

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,

for Srinivas Nandkumar, PhD
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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K181416

Device Name: **Sapphire Dorsal Comfort Fit Appliance**

Indications for Use:

The Sapphire Dorsal Comfort Fit Appliance is intended for use in patients 18 years of age or older for the reduction of night time snoring and mild to moderate obstructive sleep apnea.

Type of Use (Select one or both, as applicable)

Prescription Use __√__ AND/OR Over-the-Counter Use _____
(21 CER 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiologic Health (CDRH)

4.1

510(k) Summary

Submission Owner:	Crane Dental Laboratory Kevin Crane, President 3515 Buffalo Road, Suite 30 Rochester NY 14624 Phone: 585-730-5100 FAX: 530-730-5095 Email: kevin@cranedentallab.com
Contact Person:	Kevin Crane, President 3515 Buffalo Road, Suite 30 Rochester, NY 14624 Phone: 585-730-5100 Email: kevin@cranedentallab.com
Submission Date:	September 16, 2019
Device Name:	Trade Name – Sapphire Dorsal Comfort Fit Appliance
Regulation Description:	Intraoral device for snoring and mild to moderate obstructive sleep apnea (OSA) device, anti-snoring
Classification:	Regulation – Number 21 CFR 872.5570, Intraoral devices for snoring and obstructive sleep apnea Definition – Regulation Medical Specialty Review Panel – Dental Product Code – LRK Device Class – II

Substantial equivalence is claimed to:

Primary Predicate: SomnoMed Inc – SomnoMed MAS Flex "S" (K073004)
Reference Device: SnoreRx (K170825)

Device Description:

The Sapphire Dorsal Comfort Fit Appliance is an intraoral device used for reducing snoring and mild to moderate obstructive sleep apnea. It consists of fitted trays which fit over the upper and lower teeth. The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space during sleep and improves their ability to exchange air during sleep. The device is made for each patient and has an expansion screw adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device.

Indications for Use of the Device:

The Sapphire Dorsal Comfort Fit Appliance is intended for use in patients 18 years of age or older for the reduction of nighttime snoring and mild to moderate obstructive sleep apnea.

Intraoral gingival, palatal, or dental soreness:

As similar to the predicate device, the Sapphire Dorsal Comfort Fit Appliance is a patient-specific dental device fitted to the upper and lower arches, constructed of medical-grade acrylic to contact the teeth on the lingual, occlusal and buccal surfaces, and a small area of the supporting tissue and dental-alveolar structures during sleep. The device design distributes the force of the repositioning of the mandibular arch throughout the appliance and the entire arch and supporting structures. Because the device is designed to eliminate single point contact with individual teeth and these supporting structures, it reduces the opportunity for gingival, palatal or dental soreness. Taking dental undercuts into consideration, the device is manufactured to reduce any possible soreness to the teeth and supporting structures.

Temporomandibular Joint (TMJ) Dysfunction Syndrome:

The Sapphire Dorsal Comfort Fit Appliance increases the patient's pharyngeal space by projecting the mandible down and forward to prevent the tongue and soft tissues from impeding the airway. The appliance is adjustable using a titration key and expansion screw, which enables the jaw to be brought forward in small increments by the prescribing dentist. It is recognized by the dental community that this type of repositioning can also affect the temporomandibular joints. The prescribing dentist should evaluate the TMJ prior to prescribing the Sapphire Dorsal Comfort Fit Appliance to be sure the patient does not possess risk factors to the TMJ that may be aggravated by using the appliance. Patients do sometimes report sensation in the TMJ in the first few initial uses of the appliance but resolves with continued wear. Patients who continue to have TMJ pain or discomfort that does not resolve through continued use should decide with their dentist to discontinue treatment with this modality.

Obstruction of Oral Breathing:

The design of the Sapphire Dorsal Comfort Fit Appliance will not obstruct oral breathing.

Loosening or flaring of lower anterior teeth or general tooth movement:

Full arch coverage of the Sapphire Dorsal Comfort Fit Appliance helps to minimize these issues. The full arch design helps to reduce localized forces and pressure on individual teeth, or sections of teeth such as the lower anterior segment. The dentist can easily modify the amount of mandibular repositioning. This also helps to reduce the forces on the teeth and supporting alveolar structures.

Material Composition:

- Orthocryl Acrylic-Polymethylmethacrylate Acrylic Splints
- Durasoft: Thermoplastic polyurethane(TPU)/ Polyethylenterephthalate-Glycol Copolyester (PET-G) laminate soft lining material adhered to the hard surface acrylic
- Stainless Steel Expansion Screw

Non-Clinical Testing:

Biocompatibility testing, including cytotoxicity, sensitization, and irritation testing, was performed for the Sapphire Dorsal Comfort Fit Appliance in accordance with ISO 10993-1 and its applicable parts. Resin samples were tested for tensile per ASTM D638-14, static three-point bend per ISO 20795, fatigue three-point bend per ISO 20795, and fracture toughness per ASTM D5045. The full device assembly was challenged in a drop test to assure the integrity of the fully assembled device.

The design of the Sapphire Dorsal Comfort Fit Appliance addresses the risks outlined in the Guidance Document: *Class II Special Controls Guidance Document: Intraoral Device for Snoring and/or Sleep Apnea; Guidance for Industry and FDA* issued on November 12, 2002.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Sapphire Dorsal Comfort Fit Appliance to the predicative device.

Predicate Device Comparison:

	Proposed Device Sapphire Dorsal Comfort Fit Appliance (K181416)	**Primary Predicate Device SomnoMed MAS Flex "S" (K073004)**	**Reference Predicate Device SnoreRx (K170825)**	**Similarities and Differences**
Indications for Use	Intended for use in patients 18 years of age or older for the reduction of nighttime snoring and mild to moderate obstructive sleep apnea.	Intended to reduce or alleviate nighttime snoring and mild to moderate Obstructive Sleep Apnea (OSA).	Minimize air turbulence that causes snoring.	Same, Snore Rx not indicated for sleep apnea
Usage	Single Patient Multiple Use	Single Patient Multiple Use	Single Patient Multiple Use	Same
Patient Population	Adults age 18 and older	Adults age 18 and older	Adults age 18 and older	Same
Prescription usage	Prescription only	Prescription only	Over-the-counter	Sapphire and SomnoMed same, Snore Rx different
Basic Design	Dorsal Fin in lower advanced by orthodontic screw in upper tray	Two patient specific fitted trays which fit over the upper and lower teeth and engage by means of adjustable lugs.	Two trays which fit over the upper and lower teeth and engage by means of notched adjustable locking mechanism	Same basic design principles
Device Functionality	Increase patient's pharyngeal space to improve air exchange by repositioning the mandible	Increase patient's pharyngeal space to improve air exchange by repositioning the mandible	Increase patient's pharyngeal space to improve air exchange by repositioning the mandible	Same
Mandibular Advancement	6mm adjustment range	6mm adjustment range	6mm adjustment range	Same
Materials	Tray – hard surface acrylic	Tray – hard surface acrylic	Polycarbonate resin,	See below for

	(Dentaurum Orthocryl Liquid and Orthocryl Powder) Lining – Durasoft by Scheu Dental GmbH Expansion Screws – Stainless Steel by Dentaurum	(Dentaurum Orthocryl Liquid and Orthocryl Powder) Lining -SMH-Flex S Expansion Screws - Stainless Steel by Dentaurum	Ethylene vinyl acetate copolymer	discussion of material differences
Colorants	Blue	Pink	None	See below for discussion of material differences
Adjustability	By prescribing dentist or physician	By prescribing dentist or physician	By user	Sapphire and SomnoMed same, Snore Rx different
Design	Patient-specific	Patient-specific	Device heated and formed to patient anatomy	Sapphire and SomnoMed same, Snore Rx similar
Sterility	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile	Same
Testing	Tensile ASTM D638-14 Static 3 point bend ISO 20795 Fatigue 3 point bend ISO 20795 Fracture toughness ASTM D5045 Drop testing Cytotoxicity ISO 10993 Sensitization ISO 10993 Irritation ISO 10993	Tensile Static 3 point bend Fatigue 3 point bend Fracture toughness	Drop testing	See below for discussion of testing differences

Material Difference Discussion:

The soft inner lining for the Sapphire Dorsal Comfort Fit Appliance is fabricated from Durasoft material, whereas the material of the soft inner lining for the SomnoMed MAS Flex “S” predicate device is SMH-flex. Both devices contain this soft inner lining for patient comfort.

The colorant used in the Sapphire Dorsal Comfort Fit Appliance is blue as opposed to the pink used in the SomnoMed MAS Flex “S” predicate device. The colorant only serves as an aesthetic additive and does not add to or enhance the structural properties of the resin.

All of the materials used in manufacturing the Sapphire Dorsal Comfort Fit Appliance have been assessed for biocompatibility and are safe and effective for their intended use.

Testing Discussion

Performance data on the base resin material for the tray was performed to evaluate the properties against the predicate material. The predicate SomnoMed MAS Flex “S” (K073004) uses the same base resin formulation as the Sapphire Dorsal Comfort Fit Appliance of Dentaurum Orthocryl Liquid and Orthocryl Powder. Different colorants are added to the resin formulation between the

Sapphire Dorsal Comfort Fit Appliance and the predicate. Since the colorant only serves as an aesthetic additive and does not add to the structural properties of the resin, it was determined to compare the colored resin formula of the Sapphire Dorsal Comfort Fit Appliance against the base resin with no colorant added to serve as a worst-case challenge to the material comparison and does not affect substantial equivalence. Tensile, static three-point bend, fracture toughness, and fatigue testing were performed.

Due to the difficulty in acquiring patient specific devices of the SomnoMed MAS Flex "S" device, a similar off the shelf device was chosen for the drop test comparison. The SnoreRx device has a similar use, design, patient population, and functionality and therefore, the testing does not affect substantial equivalence to a cleared device.

Conclusion:

Based on the similarities in design, function, intended use and indications for use, the Sapphire Dorsal Comfort Fit Appliance is substantially equivalent to the identified predicate device.