510(k) Summary

OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor

1. Submission Sponsor

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3. Date Prepared

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4. Device Identification

Trade/Proprietary Name:	OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor
Common/Usual Name:	Sleep Appliances with Patient Monitoring
Classification Name:	Intraoral Devices for Snoring and /or Obstructive Sleep Apnea
Regulation Number:	872.5570

Product Code: PLC

Device Class: Class II

Classification Panel: Dental

5. Legally Marketed Predicate Device(s)

Primary Predicate
K030440 OASYS Oral/Nasal Airway System, by Dream Systems LLC

Reference Device
K083209 Acrylic Splint Herbst Appliance, by Specialty Appliances

Reference Device
K150369 SomnoDent with Micro-Recorder, by SomnoMed, Inc.

Reference Device
K170692 Respire Pink with DentiTrac, by Respire Medical LLC

Reference Device
K974727 Jet Acrylic Liquid-Monomer, Ortho Jet Powder-Polymer, Plasticized Methacrylate Homopolymer, Methacrylate Copolymer, METR, by J.B.C and CO.

Reference Device
K002048 JBC Opaque and Glitter, by J.B.C and CO.

6. Indication for Use Statement

The OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor is intended to reduce snoring and mild to moderate obstructive sleep apnea (OSA) and monitor patient usage in an adult population.

7. Device Description

The OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor are simple hardware devices. They are oral appliances and will be manufactured by a dental laboratory to and on the order of a dentist, physician or licensed practitioner. Each appliance is customized for patients.

The OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor are intra-oral devices used for treating snoring and mild to moderate Obstructive Sleep Apnea (OSA). They consists of two custom fitted trays which fit over the upper and lower dentition of a patient and engage by means of adjustable metal screws or lugs. The devices function as mandibular repositioners, which act to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep and improve their ability to exchange air. Additionally nasal dilator buttons are attached to the upper appliance, that when engaged stretch the nasio-label tissue in order to increase space in the nasal airway passage thus reducing tissue obstructions that aid in reducing

snoring and OSA.

The devices are retained on the teeth by labial and lingual positioned ball clasps, typically located in the undercuts of each splint and by the base material engaging the undercuts of the teeth.

The devices are custom made for each patient and have an adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device.

Additionally, the devices include the Dentitrac ® patient monitoring system as characterized under the Braebon Dentitrac MAF 2557 to help monitor patient compliance to prescribed usage.

8. Substantial Equivalence Discussion

The following table compares the OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor to the predicate device and reference device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device and reference devices.

Table 5A – Comparison of Characteristics

Feature	Subject OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor	Primary Predicate OASYS Oral/Nasal Airway System	Reference Predicate Device Acrylic Splint Herbst Appliance (1)	Reference Device (1) SomnoDent with Micro-Recorder	Reference Device (2) Respire Pink with DentiTrac	Comparison
510 (k) Number	K181571	K030440	K083209	K150369	K170692	Same method
Manufacturer	Dream Systems LLC	Dream Systems LLC	Specialty Appliances (Assimilated into Dream Systems LLC portfolio)	SomnoMed, Inc.	Respire Medical LLC	NA
Classification #	872-5570	872-5570	872-5570	872-5570	872-5570	Same
Product Code	Primary: PLC	Primary: LRK Secondary, LWF	Primary: LRK	Primary: PLC	Primary: PLC per Summary, LRK per FDA Website	The OASYS devices and the associated reference devices share the same product code(s). The predicate and primary predicate

						devices only reference product code LRK because they do not contain patient monitoring capability as is the subject of this submission
Indications for use	The OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor is intended to reduce snoring and mild to moderate obstructive sleep apnea (OSA) and monitor patient usage in an adult population.	OASYS Oral Airway System is intended for use to reduce or eleviate snoring and obstructive sleep apnea	The Acrylic Splint Herbst Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea. The Acrylic Splint Herbst Appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient	The SonmoDent® intraoral devices are intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. Optionally, if the DentiTrac® patient monitoring system is completely embedded into the SomnoDent® device, the patient monitoring system is intended to measure	The Respire Pink Series intraoral appliances are intended to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older. Optionally the DentiTrac® patient monitoring system may be incorporated into a Respire Pink Series device. The patient monitoring system is intended to measure patient	Similar, only minor changes in wording but the same meaning and intended use for the adult population

				patient compliance to oral device/appliance therapy in combination with the DentiTrac® System	compliance to oral appliance therapy in combination with the DentiTrac® System	
Mode of Action	These devices function as a mandibular repositioner, which acts to increase the patient's pharyngeal space, by reducing obstructions of the airway and improving their ability to exchange air during sleep. Additionally, nasal dilators are used to open the nasal pathway improving air flow through the nose and reducing soft palatal vibrations inducing snoring Finally, monitoring capability is included	This device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep by reducing mechanical obstructions of the airway. Additionally, nasal dilators are used to	This device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep by reducing mechanical	The device functions as a mandibular repositioner, which acts to improve the patient's ability to breathe, without obstruction of the pharyngeal airway Additionally, monitoring capability is included utilizing the DentiTrac® patient compliance monitoring technology.	The device functions as a mandibular repositioner, which acts to improve the patient's ability to breath without obstruction of the pharyngeal airway, Additionally, monitoring capability is included utilizing the DentiTrac® patient compliance monitoring technology.	Similar modes of action. The subject device and the predicate have the same modes of action i.e. increasing the pharyngeal space and increasing the nasal space by keeping it free of obstruction by the use of continuous gentle force to alleviate snoring and OSA. The subject device has the addition of the DentiTrac® patient compliance monitoring technology. Which the predicate device does not have. However, the DentiTrac patient compliance monitoring

	utilizing the DentiTrac® patient compliance monitoring technology. The mechanism of action is continuous gentle force stretching the nasal labial fold from under the upper lip to pull on the nasal valve and mechanically dilating the area of the nasal valve increasing airflow though the nasal valve.	open the nasal pathway improving air flow through the nose and reducing soft palatal vibrations inducing snoring The mechanism of action is continuous gentle force		The mechanism of action is continuous gentle force	The mechanism of action is continuous gentle force	technology is utilized in both Reference Devices 1 and 2. Reference devices 1 and 2 share the capability of increasing of pharyngeal space by continuous gentle force but do not share the function of increasing the nasal airway through the use of nasal dilators as this functionality is shared between the subject device and the predicate device only. As the subject device in conjunction with the predicate, reference predicate and the reference devices include no additional modes of action there is no increased risk inherent in the functionality of the subject device

Material	Heat sensitive Impression Material Rigid Tray Advancement mechanism surgical grade stainless steel DentiTrac® Patient monitoring system embedded into OASYS devices	Heat sensitive Impression Material Rigid Tray Advancement mechanism surgical grade stainless steel	Heat sensitive Impression Material Rigid Tray Advancement mechanism surgical grade stainless steel	Trays constructed from a softlining material adhered to a hard surface acrylic. Advancement mechanism is constructed of surgical grade Stainless Steel **DentiTrac® Patient monitoring system embedded into SomnoDent**	Acrylic fitting surface, Acrylic/Wironit fitting surfaces Advancement mechanism surgical grade stainless steel DentiTrac® Patient monitoring system embedded into Respire Pink Series devices	Subject device, reference predicate and predicate devices are made of an Heat sensitive impression material and rigid tray The reference device 1 is made of a softlining material adhered to acrylic, while the reference device 2 is made of acrylic. Acrylic is the bases for the rigid trays in the subject and predicate devices The Advancement devices are made of stainless steel in the subject and both reference devices. And the subject device, and 2 reference devices embed the DentiTrac® Micro-recorder

Mode of Care	Adjustable by Dentist or Physician during the duration of use	Adjustable by Dentist or Physician during the duration of use	Adjustable by Dentist or Physician during the duration of use	Adjustable by Dentist or Physician during the duration of use	Adjustable by Dentist or Physician during the duration of use	Same
Usage	Removable and Reusable by the same patient. Night Time Usage Only	Removable and Reusable by the same patient. Night Time Usage Only	Removable and Reusable by the same patient. Night Time Usage Only	Removable and Reusable by the same patient. Night Time Usage Only	Removable and Reusable by the same patient. Night Time Usage Only	Same
Biocompatible	Yes	Yes	Yes	Yes	Yes	Same
OTC or Rx	Rx	Rx	Rx	Rx	Rx	Same
Insertion	2 piece design allows for the upper appliance to be inserted first followed by the lower appliance	2 piece design allows for the upper appliance to be inserted first followed by the lower appliance	2 piece design allows for the upper appliance to be inserted first followed by the lower appliance	2 piece design allows for the upper appliance to be inserted first followed by the lower appliance	2 piece design allows for the upper appliance to be inserted first followed by the lower appliance	Two piece design allows greater ease of insertion and incurs no additional risk to the patient
Patient compliance Monitoring Capability	Yes DentiTrac® Micro-recorder	No	No	Yes DentiTrac® Micro-recorder	Yes DentiTrac® Micro-recorder	The subject device contains a DentiTrac® Patient monitoring system while the predicate device does not. However, the subject device and both reference devices use

						the DentiTrac® Micro-recorder

9. Non-Clinical Performance Data

Same as predicate. **OASYS Oral/Nasal Airway System under K030440**

And

#	Testing
1	Dentitrac ® Patient Monitoring System, biocompatibility, electrical, performance and characterization testing in MAF 2557
2	Material, physical properties and biocompatibility in K974727 and K002048

The **OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor** passed all the testing in accordance with internal requirements, applied national standards, and applied international standards shown below to support substantial equivalence of the subject device: Biocompatibility - The biological safety of the components of the OASYS were evaluated in accordance with ISO 10993-1 and guidance document entitled *Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process*". Under this, for the stated indications for use, components of the device's biological safety were evaluated for in vitro cytotoxicity, skin sensitization, and irritation, and mutagenicity and chemical characterization.

- Biocompatibility testing per ISO 10993-1 Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process: Passed
- Biocompatibility testing per ISO 10993-5 Cytotoxicity: Passed
- Biocompatibility testing HET-CAM Tests for irritation and skin sensitization: Passed
- Biocompatibility testing mutagenicity (Ames test): Passed
- Biocompatibility testing per ISO 10993-12 chemical analysis of eluted components acc.: Passed

Risk Analysis - Formal Risk Assessment of the OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor was performed in accordance with ISO 14971.

Non-clinical performance testing: The **OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor passed all internal performance testing standards.**

The addition of the DentiTrac® patient monitoring system does not adversely affect the original design, therefore, not introducing any new issues of concern. A risk assessment shows that risks are mitigated to acceptable levels, and performance testing related to the DentiTrac® patient monitoring system confirms that EMC and electrical safety, biocompatibility, and software elements were evaluated. DentiTrac® performance testing is located in the Braebon DentiTrac® Master File MAF 2557. Process validation concerning the incorporation and functionality of the DentiTrac® patient monitoring system is

certified by Braebon. Dream Systems LLC Medical performs 100% visual and functional inspections throughout the production process to ensure that the device meets manufacturing specifications for the **OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor** device and specifications for the incorporation of the DentiTrac® patient monitoring system.

10. Statement of Substantial Equivalence

The performance testing provided demonstrates that the subject device(s) is substantially equivalent to the predicate device and reference device (s). The Dream Systems LLC, OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.