DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 16, 2014

National Dentex Corporation
C/O Mr. Bradley J. Chott
Director of Operations
160 Larkin Williams Industrial Court
Fenton, MO 63026

Re: K133390
Trade/Device Name: ClearDream®
Regulation Number: 21 CFR 872.5570
Regulation Name: Device, anti-snoring
Regulatory Class: II
Product Code: LRK
Dated: October 1, 2014
Received: October 6, 2014

Dear Mr. Chott:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K133390

Device Name: ClearDream®

Indications for Use:
The ClearDream® is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary 21 CFR 807.92

510(k) Number: K133390

Manufacturer:	National Dentex Corporation (NDX) 3910 RCA Blvd. Ste. 1015 Palm Beach Gardens, FL 33410 Telephone: 636-600-4244 Fax: 636- 600-4396 E-mail:bchott@kellerlab.com
Official Correspondent:	Brad Chott Keller Laboratories fully owned subsidiary of NDX 160 Larkin Williams Industrial Court Fenton, MO 63026 Telephone: 636-600-4244 Fax: 636-600-4396 E-mail:bchott@kellerlab.com
Date Prepared:	October 9, 2014
Trade Name:	ClearDream®
Common Name:	Intraoral device for snoring and mild to moderate obstructive sleep apnea (OSA)
Classification Name:	Device, anti-snoring
Regulation Number:	21 CFR 872.5570
Product Code:	LRK
Class:	II
Panel:	Dental
Predicate Device:	K050592, Somnomed MAS RXA

Description of the device:

The ClearDream® is an intraoral dental device and is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The product is a prescription-only, customized device for use by a single patient; dentist titratable mandibular repositioning device worn during sleep to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. Dental impressions must be used to construct the device. A bite registration reflecting the relationship between the patient's mandible (lower jaw) and maxilla (upper jaw) is taken at the dental office. The product consists of 2 pieces. Both pieces are constructed using polymethyl methacrylate acrylic (PMMA). One piece fits over the maxillary (upper jaw) dental arch and is retained by the maxillary teeth. The maxillary piece has blocks of acrylic located bilaterally on the buccal surfaces. One expansion stainless steel screw is encased in each one of the acrylic blocks. The mandibular (lower jaw) piece is fitted over the mandibular arch and is retained by the lower dental arch. The mandibular piece features bilateral buccally located flanges that engage the upper mechanisms. This engagement repositions the mandible protrusively to decrease air turbulence, increase pharyngeal space, and maintain airway patency. It also permits the patient to open their mouth allowing patient comfort. The ClearDream® appliance keeps the PMMA covering the lingual surfaces of the lower teeth to a minimum. The duration of the interval of wearing the device is 8 hours or less. The PMMA material used is identical to the predicate device, and therefore does not present any possible biocompatibility differences that have been tested on the PMMA. The ClearDream® is accompanied by an adjustment

key used by the dentist. The dentist uses the adjustment key to move the bilateral, buccally-located expansion stainless steel screws allowing forward mandibular advancement a maximum from baseline of 6.5 millimeters, thereby improving patency of the airway, decreasing air turbulence, and reducing obstructive apnea occurrences.

Indications for use:

The ClearDream® is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Technological Characteristics:

The ClearDream® oral appliance has identical technical characteristics as the predicate device. Table 1 contains a basic description of the intended use, design attributes and technological characteristics demonstrating that the proposed and predicate device are identical in terms of how they achieve their intended use.

Table 1 Comparison summary to legally marketed predicate device Somnomed MAS RXA:

Intended Use	ClearDream®	Somnomed MAS RXA
Intended as an intraoral device	Yes	Yes
Intended to reduce snoring	Yes	Yes
Treatment of mild to moderate obstructive sleep apnea	Yes	Yes
Intended for nighttime use	Yes	Yes
Indicated for single patient multiuse	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes
Indicated for adult population	Yes	Yes
Design Attributes	**ClearDream®**	**Somnomed MAS RXA**
Customized fit for each specific patient	Yes	Yes
Separate upper and lower tray pieces	Yes	Yes
Bilateral design to engages the upper mechanisms	Yes	Yes
Works by mandibular advancement	Yes	Yes
Can be adjusted or refit	Yes	Yes
Lower jaw adjustment using supplied components	Yes	Yes
Permits patient to breathe through mouth	Yes	Yes

Upper and lower trays disengage for easy removal	**Yes**	**Yes**
Cleaned and inspected daily by patient	**Yes**	**Yes**
Stainless steel expansion screws to facilitate titration by dentist	**Yes**	**Yes**
Titration is done by the dentist	**Yes**	**Yes**
Material	**ClearDream®**	**Somnomed MAS RXA**
Trays constructed with polymethyl methacrylate acrylic (PMMA)	**Yes**	**Yes**
Bilaterally adjustable stainless steel hardware	**Yes**	**Yes**
Advancement mechanism constructed of surgical grade stainless steel	**Yes**	**Yes**
Mandibular piece features bilateral buccally located flanges	**Yes**	**Yes**

Non Clinical Performance Data:

The ClearDream® conforms to the requirements of the FDA Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA published on November 12, 2002. The material composition of the ClearDream polymethyl methacrylate acrylic (PMMA) medical grade has been tested and found to comply with the Standard ISO 7405 and ISO 10993 part 5 and part 10 referenced per 21 CFR 872.5570 Intraoral devices for snoring and/or obstructive sleep apnea, product code LRK. The material characteristic of the ClearDream ® appliance, meeting ASTM standards, have been found to be substantially equivalent to the predicate device material characteristics. Included in the 510K under Performance Bench Testing is evidence of the ClearDream ® component material identity, chemical composition, material safety support the requirements noted in the Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA issued November 12, 2002. The material composition, performance characteristics, technical characteristics, risks analysis, and biocompatibility of the ClearDream ® appliance and components have been addressed and found to comply with the guidance set forth in FDA Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA published on November 12, 2002 enabling the ClearDream® to meet the indications for use. A risk analysis was conducted and confirms the risks published in the FDA guidance document FDA Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA published on November 12, 2002 have been addressed and no additional risks were identified with the submission of the ClearDream®. The risk analysis did not identify any other specific risks to the ClearDream®.

Biocompatibility:

The materials and fabrication of the proposed and predicate device are identical. The material composition of the ClearDream polymethyl methacrylate acrylic (PMMA) medical grade has been

tested and found to comply with the Standard ISO 7405 and ISO 10993 part 5 and part 10 referenced per 21 CFR 872.5570 Intraoral devices for snoring and/or obstructive sleep apnea, product code LRK.

Clinical Data:

None provided in accordance with the least burdensome provisions of the FDA Modernization Act of 1997. Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA issued November 12, 2002 item 8, Clinical testing states, the agency does not request clinical studies for new devices whose intended use is identical to that of the claimed predicate device, having similar design and technology.

Substantial equivalence discussion:

National Dentex submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the ClearDream® is substantially equivalent in indications and design principles to the following predicate device Somnomed MAS RXA K050592

For the purposes of FDA's regulation of medical devices, the ClearDream® is substantially equivalent to the Somnomed MAS RXA device. Both the ClearDream® and the Somnomed MAS RXA are prescription-only, customized for one patient only for multiple use, dentist titratable mandibular repositioning devices intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The material composition, technical and functional designs as well as indications for use of each product are identical. They both require dental impressions to allow patient specific customized and fabricated acrylic trays which fit onto the upper and lower teeth and are positioned in relation to each other by adjustment mechanisms. The subject device is manufactured using polymethyl methacrylate acrylic (PMMA) and stainless steel expansion screws that conform to the FDA Class I General Controls Guidance Document. The amount of mandibular advancement for ClearDream® is one millimeter more than the predicate, however the difference is well within the range of mandibular advancement in other previously cleared FDA intraoral devices for treatment of mild to moderate sleep apnea, and titration of mandibular advancement is the responsibility of the prescribing dentist. Therefore, the slight difference in mandibular advancement of the ClearDream® device as compared to the predicate does not raise any additional concerns. There are no new safety concerns raised by the design of the ClearDream® when compared to the predicate device.

The material composition, design specifications, technical features, nonclinical testing, and performance characterizes of the ClearDream® have been demonstrated to be safe and as effective and to perform as well as or better than the predicate device.

Conclusions:

The ClearDream® has the same intended use as the predicate device, same material composition, design features and technological characteristics that do not raise different types of questions of safety and effectiveness when compared to the predicate device. We believe that the analysis provided herein supports the claim that the ClearDream® OSA appliance intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults is substantially equivalent to the predicate device.