K132003



# 2. 510(K) SUMMARY

JUN 13 2014

**Date Prepared:** June 9, 2014

**510(k) Owner Information:**
ApniCure, Inc.
900 Chesapeake Drive
Redwood City, CA 94063

**Contact Person**
Chris Daniel
Executive Vice President, Operations
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**Device Information:**

| | |
|---|---|
| Trade Name: | Winx Sleep Therapy System |
| Common Name: | Intraoral Pressure Gradient Device |
| Classification: | Class II |
| Classification Name: | Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570, Product Code OZR) |

**Physical Description:**
The Winx Sleep Therapy System consists of four (4) main components and two (2) sizing methods. The components are: a small electronic bedside console, a soft polymer mouthpiece, a flexible polymer tube that connects the mouthpiece to the console, and a physicians' software application (Winx Data Management Software) that allows clinicians to download usage data from the console and generate patient usage reports. The sizing methods include: a sizing template and an iPhone sizing application (Winx Mouthpiece Sizing Application).

The mouthpiece is an intraoral device that is worn during sleep. The system is designed to increase airway patency and decrease airway obstruction.

**Console**
The console generates a gentle negative pressure, collects excess saliva, records patient use time, and monitors pressure. The console is provided with a power cord, which connects to a standard electrical outlet. An optional laboratory console is available for use in a sleep laboratory. The laboratory console includes wires that extend from the console. The wires connect to the sleep laboratory's polysomnography (PSG) system, allowing the sleep technicians to view the console's pressure on the same monitor as the other PSG channels.

**Mouthpiece**
Two versions of the mouthpiece are provided – Winx and Winx+. The Winx+ mouthpiece includes a tongue pocket. Each mouthpiece is provided in ten (10) discrete sizes. Sleep technicians use a bite wax to obtain an impression of each patient's teeth and a sizing template or iPhone application to determine the best mouthpiece size.

**Tubing**
The tubing connects to the console and to the mouthpiece with custom connectors.

**Winx Data Management Software Application**
The Winx Data Management Software application resides on a sleep laboratory computer and allows clinicians to download usage data from the console and generate patient usage reports.

**Use**
The patient connects the system and places the mouthpiece in his or her mouth. The mouthpiece is worn during sleep. The console generates a gentle, negative pressure, which is delivered through the mouthpiece into the oral cavity and holds the tongue and soft palate out of the airway. The console records patient usage data (e.g., hours and days of use, oral cavity pressure). Clinicians can download patient usage data from the console to review usage and generate usage reports.

**Indications for Use:**
The Winx Sleep Therapy System is indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults.

**Substantial Equivalence:**
The Winx Sleep Therapy System is substantially equivalent in intended use, indications for use, and technological characteristics to the following device:

| Name | Manufacturer | 510(k) # |
|---|---|---|
| Winx Sleep Therapy System | ApniCure | K111549 |

**Technological Characteristics:**

| Characteristic | Winx Sleep Therapy System (Predicate) | Winx+ |
|---|---|---|
| K Number | K111549 | K132003 |
| Intended Use | Treatment of obstructive sleep apnea (OSA). | Same |
| Indications for Use | The Winx Sleep Therapy System is indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults. | Same |
| Target population | Adults who have obstructive sleep apnea. | Same |
| Mode of | Pressure gradient developed between | Same |

| | | |
|---|---|---|
| operation | pharyngeal airway and oral tissues urges soft palate and tongue anteriorly out of airway. Airway remains at ambient pressure while sealed oral cavity is maintained at lower pressure. Negative oral pressure supplied by the Winx Sleep Therapy System is delivered via the mouthpiece to the patient's mouth. | |
| Anatomical sites | Intraoral | Same |
| Where used | Home | Same |
| Energy used or delivered | Negative 25 inches of $H_2O$ at pump to maintain negative 20 inches of $H_2O$ in oral cavity | Negative 20 inches of $H_2O$ at pump to maintain negative 20 inches of $H_2O$ in oral cavity |
| Patient Contacting Materials | Polymers (polycarbonate, thermoplastic elastomer, Tygon tubing), adhesive | Same |
| Biocompatibility | Meets ISO 10993 | Same |
| Sterility | Non-sterile | Same |
| Electrical Safety | Meets IEC 60601-1 and 60601-1-2 | Same |
| Operating conditions | 5° to 40°C, 15% to 95% relative humidity | Same |
| Storage conditions | -20° to 60°C, 15% to 95% relative humidity | Same |
| Vacuum area shape | Flat bar with multiple vacuum ports | Curved bar with 1 vacuum port |
| Lip seal shape | No tongue pocket | Tongue pocket |

**Non-Clinical Performance Data:**
Design verification & validation testing were performed on the Winx Sleep Therapy System using the Winx+ Mouthpiece.

The test protocols were developed based on product requirements, specifications, and risk analyses. ApniCure uses a Failure Mode and Effect Analysis (FMEA) to assess the impact of proposed device modifications. Non-clinical testing is summarized below.

| Test | Test Method Summary | Results |
|---|---|---|
| Design verification | Verify system meets its engineering specifications, including performance, strength, reliability, life, and component compatibility. | Pass |
| Electrical | Verify console passes electrical safety and EMC testing per IEC 60601-1 and 60601-1-2. Safety testing includes leakage currents, dielectric strength, mechanical strength, excessive temperatures, fire prevention, liquid overflow, and interruption of the power supply. EMC testing includes conducted and radiated emissions, electrostatic discharge, radiated immunity, and surge. | Pass |

| | | |
|---|---|---|
| Biocompatibility | Verify mouthpiece passes biocompatibility testing per ISO 10993-1. Specifically, cytotoxicity, sensitization, and oral irritation. | Pass |
| Environmental | Verify system passes environmental testing. | Pass |
| Shipping | Verify system passes shipping testing per D4169-09. | Pass |
| Acoustics | Verify system passes acoustics testing per ISO 7779. | Pass |

Results of non-clinical testing demonstrate that the Winx Sleep Therapy System using the Winx+ Mouthpiece is as safe and as effective for its intended use and substantially equivalent to the predicate.

**Clinical Performance Data:**

*Materials, Methods, and Study Population*
Subjects were enrolled in two studies to evaluate the effectiveness and safety of the Winx+ mouthpiece. The first study was a randomized, crossover study comparing first night effectiveness and safety after four nights of home use between the Winx and Winx+ mouthpieces using subjects who were naïve to both treatments (Randomization Study). The second study was a thirty-day extension using the Winx+ mouthpiece at home followed by a second treatment PSG and safety evaluation (Extension Study).

The subject population included otherwise healthy subjects with OSA. Male and female subjects between the ages of 18 and 80 were included without discrimination by gender, and subjects of all races and ethnicities were equally eligible to participate in the studies.

*Results*

*Effectiveness*
The Primary Endpoint was defined as Clinical Success on treatment night determined by apnea-hypopnea index (AHI) and defined as AHI reduction of $\geq$ 50% comparing treatment PSG to control PSG and treatment AHI $\leq$ 20 events per hour.

**Randomization Study Subjects Meeting Clinical Success on First Treatment Night**

| Measure | Winx Mouthpiece | Winx+ Mouthpiece |
|---|---|---|
| Clinical Success Subjects | 12 of 30 | 19 of 30 |
| Success Rate | 40.0% | 63.3%* |

*P<0001 for the test of non-inferiority of Winx+ against Winx based on the two-sample one-sided Z test for two proportions against delta=-0.20.

**Extension Study Subjects Meeting Clinical Success on Last Treatment Night**

| Measure | Winx+, Last Night |
|---|---|
| Clinical Success Subjects | 18 of 23 |
| Success Rate | 78.3%* |

*P<0.001 for the test of non-inferiority against the proportion of 40% with delta of -0.20.

*Safety*
During treatment with the Winx+ mouthpiece, there were no serious or severe adverse events (AEs) reported. Seventy-five percent (75%) of the AEs were classified as mild in severity

(awareness of sign or symptom but easily tolerated; for example, a noted transient redness on tongue after removal of device) and twenty-five percent (25%) of the AEs were classified as moderate in severity (discomfort enough to cause interference with usual activity; for example, a subject with a sore mouth who had discomfort/difficulty drinking orange juice).

Ten (10) events (oral tissue irritations/discomforts and dental discomforts) were treated with over-the-counter medication. One (1) subject had gum inflammation that was self-treated by gargling salt water. All AEs resolved without need of medical intervention or prescription medication. The mean duration of device-related AEs was 8.4±9.3 days (mean±SD), median (Q1, Q3) of 6 (3, 8) with a range of 1-38 days.

**Listing of Device-Related Adverse Events for Winx+ Mouthpiece**

| |
|---|
| Oral Tissue Irritation with Discomfort |
| Oral Tissue Irritation without Discomfort |
| Oral Tissue Discomfort without Irritation |
| Dental Discomfort |
| Dry Mouth |
| Excessive Salivation |
| Jaw Discomfort |
| Headache |
| Nasal congestion |
| Other<br>• Cold<br>• Tight and numb feeling in mouth<br>• Mouth felt stretched out<br>• Tooth sensitivity<br>• Color of tongue<br>• Excessive mucous<br>• Sore neck<br>• Diminished sense of taste<br>• Jaw alignment change |

*Discussion*

The objective of the Randomization and Extension Studies was to demonstrate that the safety and effectiveness of the Winx+ mouthpiece when used with the Winx Sleep Therapy System is substantially equivalent to the safety and effectiveness of the predicate Winx mouthpiece when used with the Winx Sleep Therapy System. The thirty-day home-use period was completed by 24 of 29 subjects who initiated it. No new safety issues were identified, there were no serious or severe AEs, and no medical interventions for AEs were required.

The effectiveness endpoints were met with $p<0.001$, demonstrating the non-inferiority of the effectiveness of the Winx+ mouthpiece during the first and last treatment nights when compared

to the Winx mouthpiece evaluated during the first treatment night in the Randomization Study and after a twenty-eight-day home-use period in the pivotal study of the predicate device.

*Conclusion*
The safety and effectiveness of the Winx Sleep Therapy System using the Winx+ mouthpiece were evaluated and found to be substantially equivalent to the Winx mouthpiece used with the Winx Sleep Therapy System previously cleared by FDA.

**Summary:**
Based on the indications for use and product performance provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

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

June 13, 2014

ApniCure, Inc.
Chris Daniel
Executive Vice President, Operations
900 Chesapeake Drive
Redwood City, CA 94063

Re: K132003
Trade/Device Name: Winx Sleep Therapy System
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: II
Product Code: OZR
Dated: May 15, 2014
Received: May 16, 2014

Dear Mr. Daniel:

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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

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Center for Devices and
Radiological Health

Enclosure

# 1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Winx Sleep Therapy System

Indications for Use:

The Winx Sleep Therapy System is indicated for home use in the treatment of 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) |
|---|---|---|

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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