2. 510(K) SUMMARY K122130

Date Prepared: July 16, 2012

OCT 31 2012

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

Contact Person
Chris Daniel
Executive Vice President,
Operations
Phone Number: (650) 361-9300
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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: 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 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
The 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 to determine the best mouthpiece size.

Tubing
The tubing connects to the console by screwing into the console base and to the mouthpiece with luer 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) #
Attune Sleep Apnea System	ApniCure	K111549

Performance Data:
Results of bench testing demonstrate that the Winx Sleep Therapy System is safe and effective for its intended use and substantially equivalent to the predicate.

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 Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 31 2012

ApniCure, Incorporated
Mr. Chris Daniel
Executive Vice President
900 Chesapeake Drive
Redwood City, California 94063

Re: K122130
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: September 28, 2012
Received: October 1, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122130

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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices
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