

Section 6**510(k) Summary**

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: Consumer Health Products, Inc.
17 Brownsbury Road #110
Laguna Niguel, CA 92677

CONTACT : Gary Mocnik
49 Coastal Oak, Aliso Viejo, CA 92656
949.433.0413
949.831.9944 fax
gmocnik@cox.net

DATE PREPARED July 25, 2011

TRADE NAME: SnoreRx NS 9.0

COMMON NAME: Anti-Snoring Mouth Piece

CLASSIFICATION NAME: Anti-Snoring Device, 21 CFR, 872.5570

DEVICE CLASSIFICATION: Class II

PRODUCT CODE LRK

PREDICATE DEVICES: SnoreGuard (K103004), Silencer (K954530), SnoreControl (K963591), SnoreMaster (K954128)

Substantially Equivalent To:

The Consumer Health Products SnoreRx NS 9.0 is substantially equivalent in intended use, principal of operation and technological characteristics to the SnoreGuard (K103004), the Silencer (K954530), the SnoreControl (K963591), and the SnoreMaster (K954128), as well as other predicate devices cleared with an LRK Product Code.

Description of the Device Subject to Premarket Notification:

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Section 6**510(k) Summary****Indication for Use:**

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Discussion of Technological Characteristics:

The Consumer Health Products SnoreRx NS 9.0 has similar physical and technical characteristics to the predicate devices. The Consumer Health Products SnoreRx NS 9.0 and the identified predicates all provide means for advancing the lower jaw in a predetermined manner. The technical designs and manufacture of the SnoreRx NS 9.0 and the predicate devices are very similar, being composed of custom fitted acrylic trays which fit onto the upper and lower teeth and which are positioned in relation to each other by an adjustable mechanism.

Non-Clinical Performance Data:

Performance testing was conducted to evaluate and characterize the performance of the Consumer Health Products SnoreRx NS 9.0. Preclinical testing conducted included dimensional conformance evaluation, visual inspections, design verification testing to confirm airway passage equivalency, and biocompatibility testing of device materials based on the applicable elements of ISO 10993-1 shown below.

Test Performed	Standard	Test Result/Conclusion
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	ISO 10993-5	Passed. Non-cytotoxic.
ISO Intracutaneous Irritation Test	ISO 10993-10	Passed. Non-irritant
Sensitization: Guinea Pig Maximization	ISO 10993-10	Passed/Negative for evidence of sensitization

Additionally material characterization testing was performed and concluded that the materials used in the construction of the Consumer Health Products SnoreRx NS 9.0 are identical the listed predicate device.

Clinical Data

This submission does not rely on clinical data to determine substantial equivalency to the predicate devices.

Basis for Determination of Substantial Equivalence:

The following table displays the differences and similarities between the new SnoreRx NS 9.0 and other previously marketed devices.

Product	Intended Use	Principle of Operation	Overall Technological Characteristics
Consumer Medical	The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age	Provides for mandibular	Custom fitted plastic intraoral

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Section 6**510(k) Summary**

Products SnoreRx NS 9.0	or older as an aid for the reduction of snoring.	repositioning to increase pharyngeal space	device inserted over the upper and lower dental arches.
SnoreGuard (K103004)	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	SAME	SAME
Silencer (K954530)	Intended to reduce or eliminate night time snoring in patients 18 years of age or older only.	SAME	SAME
SnoreControl (K963591)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME
SnoreMaster (9541285)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME

Conclusions Drawn

As shown, the Consumer Health Products SnoreRx NS 9.0 has the following similarities to the predicate devices:

- Same intended use
- Same design characteristics
- Same operating principal
- Same mechanism of action
- Same technological characteristics

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Consumer Health Products SnoreRx NS 9.0 is determined to be substantially equivalent to existing legally marketed devices, performs as well as the predicate devices, and is as safe and effective for its intended use.

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification



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

Consumer Health Products, Incorporated
C/O Mr. Gary Mocnik
Regulatory Consultants
Gary Mocnik and Associates
49 Coastal Oak
Aliso Viejo, California 92656

NOV 16 2011

Re: K112205
Trade/Device Name: SnoreRx NS 9.0
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: LRK
Dated: November 4, 2011
Received: November 7, 2011

Dear Mr. Mocnik:

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.

Page 2 – Mr. Mocnik

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,



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

K112205

Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: SnoreRx NS 9.0

Indications for Use:

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

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

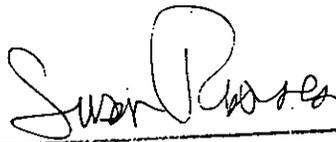
Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use _____
(Optional Format 1-2-96)

Page ___ of ___



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

510(k) Number: K112205



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

Consumer Health Products, Incorporated
C/O Mr. Gary Mocnik
Regulatory Consultants
Gary Mocnik and Associates
49 Coastal Oak
Aliso Viejo, California 92656

NOV 16 2011

Re: K112205

Trade/Device Name: SnoreRx NS 9.0

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: LRK

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Page 2 – Mr. Mocnik

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Sincerely yours,



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

K112205

Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: SnoreRx NS 9.0

Indications for Use:

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

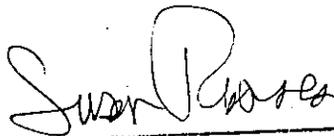
Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use _____
(Optional Format 1-2-96)

Page ___ of ___



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

510(k) Number: K112205



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 07, 2011

CONSUMER HEALTH PRODUCTS, INC
C/O GARY MOCNIK AND ASSOCIATES
49 COASTAL OAK
ALISO VIEJO, CALIFORNIA 92656
ATTN: GARY MOCNIK

510k Number: K112205

Product: SNORERX 9.0

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Nichols, Karl *

From: Microsoft Exchange
To: 'gmocnik@cox.net'
Sent: Thursday, November 03, 2011 9:31 AM
Subject: Relayed: K112205- Hold Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'gmocnik@cox.net'

Subject: K112205- Hold Letter

Sent by Microsoft Exchange Server 2007



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 03, 2011

CONSUMER HEALTH PRODUCTS, INC
C/O GARY MOCNIK AND ASSOCIATES
49 COASTAL OAK
ALISO VIEJO, CALIFORNIA 92656
ATTN: GARY MOCNIK

510k Number: K112205

Product: SNORERX 9.0

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDModerizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Williams, Michael *

From: gmocnik@cox.net
Sent: Wednesday, October 05, 2011 11:44 AM
To: Williams, Michael *
Subject: Delivered: Hold Letter for K112205

Attachments: ATT00001



ATT00001 (147 B)

Your message was delivered to the recipient.

Williams, Michael *

From: Microsoft Exchange
To: 'gmocnik@cox.net'
Sent: Wednesday, October 05, 2011 11:29 AM
Subject: Relayed: Hold Letter for K112205

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'gmocnik@cox.net'

Subject: Hold Letter for K112205

Sent by Microsoft Exchange Server 2007



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 05, 2011

CONSUMER HEALTH PRODUCTS, INC
C/O GARY MOCNIK AND ASSOCIATES
49 COASTAL OAK
ALISO VIEJO, CALIFORNIA 92656
ATTN: GARY MOCNIK

510k Number: K112205

Product: SNORERX 9.0

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Records processed under FOIA Request # 2015-0181, Released by CDRH on 11-30-2015
Please remember that the Safe Medical Device Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 02, 2011

CONSUMER HEALTH PRODUCTS, INC
C/O GARY MOCNIK AND ASSOCIATES
49 COASTAL OAK
ALISO VIEJO, CALIFORNIA 92656
ATTN: GARY MOCNIK

510k Number: K112205

Received: 8/1/2011

Product: SNORERX 9.0

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

510(k) PREMARKET NOTIFICATION
SnoreRx NS 9.0

APPLICANT

Consumer Health Products, Inc.
17 Brownsbury Road #110
Laguna Niguel, CA 92677

OFFICIAL CORRESPONDENT

Gary Mocnik
Phone: 949.433.0413
Email: gmocnik@cox.net

**CONSUMER HEALTH PRODUCTS SNORERx NS 9.0
510(K) PREMARKET NOTIFICATION**

TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE</u>
TABLE OF CONTENTS.....	2
1. COVER SHEETS (FORM FDA 3601 AND FDA 3514).....	4
2. CERTIFICATION OF COMPLIANCE WITH CLINICALTRIALS.GOV FDA FORM 3674	11
3. STANDARDS DATA REPORT FDA FORM 3654.....	13
4. COVER LETTER.....	16
5. INDICATIONS FOR USE STATEMENT.....	19
6. 510(K) SUMMARY.....	20
Description of the Device Subject to Premarket Notification:	20
Indication for Use:	21
Technical Characteristics:	21
Performance Data:.....	21
Basis for Determination of Substantial Equivalence:	21
7. TRUTHFUL AND ACCURATE STATEMENT.....	23
8. CLASS III SUMMARY AND CERTIFICATION.....	24
9. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT.....	25
10. DECLARATION OF CONFORMITY & SUMMARY REPORTS.....	26
11. EXECUTIVE SUMMARY.....	29
Device Description.....	29
Intended Use	29
Predicate Devices.....	29
Performance Testing	30
12. DEVICE DESCRIPTION.....	31
Device Construction.....	38
13. SUBSTANTIAL EQUIVALENCE DISCUSSION.....	39
14. PROPOSED LABELING.....	45
14.1 Primary Labeling	45
14.2 Draft Instructions for use	46

15. STERILIZATION AND SHELF LIFE.....	49
16. BIOCOMPATIBILITY.....	50
17. SOFTWARE.....	80
18. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY	81
19. PERFORMANCE TESTING	82
20. PERFORMANCE TESTING- ANIMALS	86
21. CLINICAL DATA.....	87

APPENDICES

Appendix 1 Predicate Device Information

Section 1

Health Device User Fee cover Sheet

1. Cover Sheets (Form FDA 3601 and FDA 3514)

(See Attached)

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

178

FDA Form 3601

Form Approved: OMB No. 0910-011. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover-sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) APNEA SCIENCES CORPORATION 17 Brownsbury Rd Laguna Niguel CA 926779382 US		2. CONTACT NAME James Cronin 2.1 E-MAIL ADDRESS jameshchronin@gmail.com 2.2 TELEPHONE NUMBER (include Area code) 949-240-3260 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)			
<u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)			
<input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA 4.1 If Yes, please enter your Small Business Decision Number: SBD110148		<input type="checkbox"/> NO, I am not a small business	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?			
<input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (if so, the application is subject to the fee that applies for an original premarket approval application (PMA).)			
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor, Rockville, MD 20850 (Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.)			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION		(b) (4)	
		12-Jul-2011	

Form FDA 3601 (01-2007)

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees

Pay.gov Tracking ID: (b) (4)

Agency Tracking ID: (b) (4)

Transaction Date and Time: 07/12/2011 15:55 EDT

Payment Summary

Account Holder Name: APNEA SCIENCES CORPORATION

Payment Amount: (b) (4)

Account Type: Business Checking

Routing Number: (b) (4)

Account Number: (b) (4)

Check Number: (b) (4)

Payment Date: 07/13/2011

**CONFIRMATION OF FDA
510K APPLICATION PAYMENT**

FDA Form 3514

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.	
Date of Submission July 25, 2011		User Fee Payment ID Number (b)(4)		FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION					
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement		PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other		PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	
		510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party		Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):	
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement		Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment		Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	
		Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information		Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):	
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)					
SECTION B SUBMITTER, APPLICANT OR SPONSOR					
Company / Institution Name Consumer Health Products, Inc. A Division of ASC			Establishment Registration Number (if known)		
Division Name (if applicable)			Phone Number (including area code) 949-226-4421		
Street Address 17 Brownsbury Road #110			FAX Number (including area code) 928-569-5974		
City Laguna Niguel		State / Province CA	ZIP/Postal Code 92677	Country USA	
Contact Name Jim Fallon					
Contact Title President			Contact E-mail Address		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)					
Company / Institution Name Gary Moczniak and Associates					
Division Name (if applicable)			Phone Number (including area code) 949-433-0413		
Street Address 49 Coastal Oak			FAX Number (including area code) 949-831-9944		
City Aliso Viejo		State / Province CA	ZIP Code 92656	Country	
Contact Name Gary Moczniak					
Contact Title Regulatory Consultant			Contact E-mail Address gmoczniak@cox.net		

FORM FDA 3514 (12/10)

Page 1 of 5 Pages

FDA OIG (10) 000-07-00 EF

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

Section 1

Health Device User Fee cover Sheet

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:	<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address				
<input type="checkbox"/> Other Reason (specify):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final					
<input type="checkbox"/> Other Reason (specify):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

Section 1

Health Device User Fee cover Sheet

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed						Summary of, or statement concerning, safety and effectiveness information	
1	LRK	2		3		4	
5		6		7		8	
						<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	
Information on devices to which substantial equivalence is claimed (if known)							
	510(k) Number		Trade or Proprietary or Model Name				Manufacturer
1	K050592	1	SonoGuard	1			Sonnomed
2	K954530	2	Silencer	2			Silent Knights Ventures
3	K963591	3	SnoreControl	3			Kenneth Hilson
4		4		4			
5		5		5			
6		6		6			
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification name							
Anti-Snoring Device							
	Trade or Proprietary or Model Name for This Device					Model Number	
1	SnoreRx NS 9.0					1	
2						2	
3						3	
4						4	
5						5	
FDA document numbers of all prior related submissions (regardless of outcome)							
1	2	3	4	5	6	7	8
7	8	9	10	11	12		
Data Included in Submission							
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials							
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS							
Product Code		C.F.R. Section (if applicable)			Device Class		
LRK		87.5570			<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified		
Classification Panel							
Anesthesiology, General Hospital, Infection Control, Dental Devices							
Indications (from labeling)							
The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring.							

Section 1

Health Device User Fee cover Sheet

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name (b) (4)		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address (b) (4)		FAX Number (including area code)	
City (b) (4)		State / Province (b) (4)	ZIP Code Country
Contact Name (b) (4)		Contact Title (b) (4)	
		Contact E-mail Address	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code Country
Contact Name		Contact Title	
		Contact E-mail Address	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code Country
Contact Name		Contact Title	
		Contact E-mail Address	

FORM FDA 3514 (12/10)

Add Continuation Page Page 4 of 5 Pages

Consumer Health Products, Inc.
 SnoreRx NS 9.0

Premarket Notification

184

Section 1

Health Device User Fee cover Sheet

SECTION 1. UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993	ISO	Biological Evaluation		
2					
3					
4					
5					
6					
7					
Please include any additional standards to be cited on a separate page.					
<p>Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>					

FORM FDA 3514 (12/10)

Page 5 of 5 Pages

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

Section 2

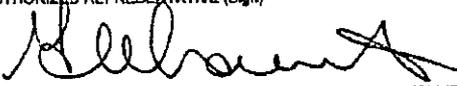
Certification of Compliance- ClinicalTrials.gov

2. *Certification of Compliance with ClinicalTrials.gov FDA Form 3674*
(See attached)

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

See OMB Statement on Reverse Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

 DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))		
(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)		
SPONSOR / APPLICANT / SUBMITTER INFORMATION		
1. NAME OF SPONSOR/APPLICANT/SUBMITTER Consumer Health Products, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 07/25/2011	
3. ADDRESS (Number, Street, State, and ZIP Code) 17 Brownsbury Road #110 Laguna Niguel, CA 92677	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 949-226-4421 (Fax)	
PRODUCT INFORMATION		
5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)		
Anti Snoring Device, 21 CFR 872.5570 Product Code LRK	Consumer Health Products SnoreRx NS 9.0	
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other		
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (if number previously assigned)		
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES		
CERTIFICATION STATEMENT / INFORMATION		
9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)		
<input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.		
<input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.		
<input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.		
10. IF YOU CHECKED BOX C. IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)" UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)		
NCT Number(s):		
The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.		
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.		
11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Gary Moczlik (Title) Regulatory Consultant	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 49 Coastal Oak Aliso Viejo, CA 92656	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 949-433-0413 (Fax) 949-831-9944	15. DATE OF CERTIFICATION 07/25/2011

FDA-3674 (1/08) (FRONT)

FDC Graphics (061) 443-1000 EP

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

Section 3

Standards Data Report Form(s)

3. *Standards Data Report FDA Form 3654*

(See attached)

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-1 Biological Evaluation of Medical Device- Part I Evaluation and Testing (2003)		
<i>Please answer the following questions</i>		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		# 02-98
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?		<input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Title of guidance: <u>G-95 Blue Book Memorandum: Use of ISO 10993-1</u>		
<small> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </small>		

FORM FDA 3654 (9/07)

Page 1

FDA Graphics (7-01) 443-1870 EF

Consumer Health Products, Inc.
 SnoreRx NS 9.0

Premarket Notification

Section 3

Standards Data Report Form(s)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-1 Biological Evaluation of Medical Device- Part 1 Evaluation and Testing (2003)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All	SECTION TITLE All	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* See attached description of compliance located in section 16 of this 510k submission		
DESCRIPTION See attached description of compliance located in section 16 of this 510k submission		
JUSTIFICATION See attached description of compliance located in section 16 of this 510k submission		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

FORM FDA 3654 (9/07)

Page 2

Consumer Health Products, Inc.
SnoreRx NS 9.0

Premarket Notification

190

4. Cover Letter
(See attached)

7/12/2011

July 25, 2011

Food and Drug Administration
 Center for Device and Radiological Health
 Document Mail Center (WO66-0609)
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

FDA CDRH DMC

AUG 1 - 2011

RE: **510(k) Notification - Abbreviated
 SnoreRx NS 9.0**

Received

To whom it may concern:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), this letter is provided to notify the Food and Drug Administration ("FDA" or the "agency") of the intention of Consumer Health Products, Inc., to manufacture and market the SnoreRx NS 9.0 device. Consumer Health Products believes the appropriate classification of the device to be:

Class II, Anti-Snoring Device, under 21 CFR 872.5570, Product Code: LRK

Consumer Health Products is submitting this Abbreviated 510(k) Notification in accordance with 21 CFR 807, Subpart E. Two (2) copies of this submission are included with this correspondence.

This submission is an abbreviated 510(k) submission. A declaration of conformity to design controls and to design verification activities is included. Additionally, the guidance document "*Class II Special controls Guidance document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA, November 12, 2002*" was used during the development of the device to address the risks associated with this particular device type described in the guidance document.

The design and use of the Consume Health Products SnoreRx NS 9.0 is presented below in tabular form:

Question	Yes	No
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X

Consumer Health Products, Inc.
 SnoreRx NS 9.0

Premarket Notification

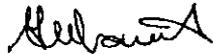
Question	Yes	No
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The existence of this Premarket Notification and the data and other information that it contains are confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

All questions and/or comments concerning this submission should be made to:

Gary Mocnik
49 Coastal Oak
Aliso Viejo, CA 92656
949.433.0413
gmocnik@cox.net

Sincerely,



Gary Mocnik
Official Correspondent for Consumer Health Products

5. **Indications for Use Statement**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: SnoreRx NS 9.0

Indications for Use:

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use _____
(Optional Format 1-2-96)

Page ___ of ___

Section 6**510(k) Summary****6. 510(k) Summary**

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: **Consumer Health Products, Inc.**
A Division of ASC
 17 Brownsbury Road #110
 Laguna Niguel, CA 92677

CONTACT : Gary Mocnik
 49 Coastal Oak, Aliso Viejo, CA 92656
 949.433.0413
 949.831.9944 fax
 gmocnik@cox.net

DATE PREPARED July 25, 2011

TRADE NAME: SnoreRx NS 9.0

COMMON NAME: Anti-Snoring Mouth Piece

CLASSIFICATION NAME: Anti-Snoring Device, 21 CFR, 872.5570

DEVICE CLASSIFICATION: Class II

PRODUCT CODE LRK

PREDICATE DEVICES: SnoreGuard (K050592), Silencer (K954530), SnoreControl (K963591)

Substantially Equivalent To:

The Consumer Health Products SnoreRx NS 9.0 is substantially equivalent in intended use, principal of operation and technological characteristics to the SnoreGuard (K050592), the Silencer (K954530), and the SnoreControl (K963591), as well as other predicate devices cleared with an LRK Product Code.

Description of the Device Subject to Premarket Notification:

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce or eliminate snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep

Section 6**510(k) Summary****Indication for Use:**

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring.

Technical Characteristics:

The Consumer Health Products SnoreRx NS 9.0 has similar physical and technical characteristics to the predicate devices. The Consumer Health Products SnoreRx NS 9.0 and the identified predicates all provide means for advancing the lower jaw in a predetermined manner. The technical designs and manufacture of the SnoreRx NS 9.0 and the predicate devices are very similar, being composed of custom fitted acrylic trays which fit onto the upper and lower teeth and which are positioned in relation to each other by an adjustable mechanism.

Performance Data:

Performance testing was conducted to evaluate and characterize the performance of the Consumer Health Products SnoreRx NS 9.0. Preclinical testing conducted included dimensional conformance evaluation, visual inspections, design verification and biocompatibility testing based on the applicable elements of ISO 10993-1 shown below.

Test Performed	Standard	Test Result/Conclusion
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	ISO 10993-5	Passed. Non-cytotoxic
ISO Intracutaneous Irritation Test	ISO 10993-10	Passed. Non-irritant
Sensitization: Guinea Pig Maximization	ISO 10993-10	Passed/Negative for evidence of sensitization

Basis for Determination of Substantial Equivalence:

The following table displays the differences and similarities between the new SnoreRx NS 9.0 and other previously marketed devices.

Product	Intended Use	Principle of Operation	Overall Technological Characteristics
Consumer Medical Products SnoreRx NS 9.0	The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring.	Provides for mandibular repositioning to increase pharyngeal space	Custom fitted plastic intraoral device inserted over the upper and lower dental arches.
SomnoGuard (K050592)	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	SAME	SAME
Silencer (K954530)	Intended to reduce or eliminate night time snoring in patients 18 years of age or older only.	SAME	SAME
SnoreControl (K963591)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

196

Section 6

510(k) Summary

As shown, the Consumer Health Products SnoreRx NS 9.0 has the following similarities to the predicate devices:

- Same intended use
- Same design
- Same operating principal
- Same mechanism of action
- Same technological characteristics

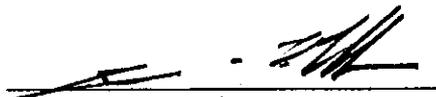
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Consumer Health Products SnoreRx NS 9.0 is determined by Consumer Health Products, to be substantially equivalent to existing legally marketed devices

Section 7

Truthful & Accurate Statement

7. Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(j), I certify that in my capacity as President of Consumer Health Products, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



James Fallon

7-25-2011

Consumer Health Products, Inc.
A Division of ASC

8. *Class III Summary and Certification*

The consumer Health Products SnoreRx NS 9.0 is a class II Health device regulated under 21 CFR §892.5700. The Class III Summary and Certification requirement as described in 21 CFR §807.87(j) and §807.94 do not apply to this device and submission.

Section 9

**Financial Certification
or Disclosure Statement**

9. *Financial Certification or Disclosure Statement*

The requirement for financial certification or disclosure requirement as described in 21 CFR §807.87(i) does not apply to this submission.

Section 10**Declaration of Conformity
& Summary Reports**

10. Declaration of Conformity & Summary Reports

This submission is an abbreviated 510(k) submission. A declaration of conformity to design controls and to design verification activities is attached. Additionally, the guidance document "*Class II Special controls Guidance document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA, November 12, 2002*" was used during the development of the device to address the risks associated with this particular device type described in the guidance document. A complete Risk Assessment based on the elements described in ISO 14971 has been conducted that includes the specific risks identified in the above referenced guidance document as well as other risks associated with the use of this type of device. This risk assessment concludes that there are no new safety concerns raised by the design of the SnoreRx NS 9.0. The following summarizes these risks and describes the mitigation measures taken

1.) **Risk of Hardware in Design:** SnoreRx NS 9.0 utilizes no hardware, of any kind that could become loose and compromise the patient. Because NS 9.0 does not incorporate any associated hardware, the risk of loose hardware is mitigated through design.

2.) **Risk of Obstruction of Oral Breathing:** Patients with a deviated septum, or cold may have a blocked nasal airway and have trouble breathing. There are two large air channels in the front of SnoreRx NS 9.0 to promote adequate airflow through the mouth therefore mitigating this risk. Independent tests by CIRO confirm adequate airflow.

3.) **Risk of Tooth Movement, or Changes In Dental Occlusion:** Improper overbite micro adjustment may cause discomfort and/or tooth movement. SnoreRx NS 9.0 is designed with micro adjustment to accommodate overbite. Once the micro adjustment is made, it is locked in, but may be changed in the future as needed. Achieving proper bite alignment assures greater comfort. Bite adjustment is recorded on the side of the product, for quick reference. The Instruction Manual contains language that says if patient experiences pain, or discomfort check/reset the adjustment, or discontinue use. The adjustment feature along with the labeling provides mitigation of any tooth movement or dental occlusion risk

5.) **Risk of Sensitivity:** The Health grade plastics have been chosen for their inherent long term safety record. Should a patient experience pain, or sensitivity the Instruction Manual advises to discontinue use. Biocompatible material selection and labeling mitigate this risk.

6.) **Risk of Pain, or Soreness to the Temporomandibular Joint:** SnoreRx NS 9.0 was specifically designed to eliminate the use of torsion, or tension to constantly pull the lower jaw forward. SnoreRx NS 9.0 uses no rubber bands, or constant tension, or torsion to pull the lower jaw forward. The micro adjustment of SnoreRx NS 9.0 assures proper fit, and permanently sets it to each patient. The Instruction Manual instructs the patient to discontinue use if the patient experiences pain, or discomfort. The device design and the associated labeling provides mitigation of this risk.

Section 10

**Declaration of Conformity
& Summary Reports**

7.) Risk of Excess Salivation: Some patients may initially experience greater salivation during its first week's use. Most patients with this condition will decrease their salivation over time. The instruction manual advises that excess salivation may be present during initial use. It further cautions that if pain or discomfort are experienced, to discontinue use. Excess salivation is not considered a health risk.

8.) Risk of Gingival or Dental Soreness: SnoreRx NS 9.0 was designed with a lower sidewall to reduce/eliminate contact with gums. The Instruction Manual identifies patients with a pre condition of gingivitis, or teeth sensitivity are not candidates to use SnoreRx NS 9.0. The device design feature along with the associated labeling mitigates this risk.

9.) Risk of Use by More Than One Patient: The custom thermal fit design limits the SnoreRx to one specific patient. Because it is custom fit to only one patient, it will not fit another patient properly. The Instruction Manual clearly identifies that no other patient other than the original user may use the product.

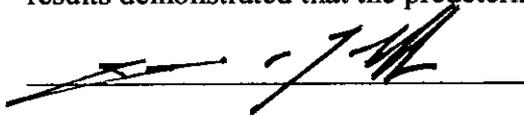
10.) Risk to a Pediatric Patient: A person under 18 years of age may have trouble following the directions, or fully understand those patients that are excluded. The Instruction Manual clearly identifies it is not intended for use by anyone under the age of 18.

11.) Risk of Patients with contraindications: Patients may use SnoreRx NS 9.0 who are not candidates to use it. The Instruction Manual identifies those patients that are not candidates for using SnoreRx NS 9.0 therefore mitigating this risk:

- Patients with sleep apnea
- Patients under the age of 18
- Patients with a history of TMD, temporomandibular disorder
- Patients who have had teeth implants within the past year
- Patients who wear dentures
- Patients with loose teeth, abscesses, or severe gum disease
- Patients undergoing orthodontic treatment
- Patients with chronic asthma, emphysema, or any respiratory disorder

**DECLARATION OF CONFORMITY WITH DESIGN
CONTROLS**

To the best of my knowledge, the verification activities, as required by the risk analysis, for the development were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



James Fallon
President

7-1-11

Date

The manufacturing facility utilized for the design and development is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



Larry Rissor
Director of Operations

7-15-11

Date

Section 11**Executive Summary****11. Executive Summary****Executive Summary*****Device Description***

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce or eliminate snoring by advancing the lower jaw and thereby minimizing. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner , which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep.

Intended Use

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring.

Predicate Devices

The Consumer Health Products "SnoreRx NS 9.0" is substantially equivalent in intended use, principal of operation and technological characteristics to the typical devices cleared under Product Code LRK as well as those listed below

A summary of the substantial equivalence between the Consumer Health Products "SnoreRx NS 9.0" and the predicates is found in the table below.

Substantial Equivalence Table

Product	Intended Use	Principle of Operation	Overall Technological Characteristics
Consumer Health Products SnoreRx NS 9.0	The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring.	Provides for mandibular repositioning to increase pharyngeal space	Custom fitted plastic intraoral device inserted over the upper and lower dental arches.
SomnoGuard (K050592)	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	SAME	SAME
Silencer (K954530)	Intended to reduce or eliminate night time snoring in patients 18 years of age or older only.	SAME	SAME
SnoreControl (K963591)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME

Consumer Health Products, Inc
SnoreRx NS 9.0

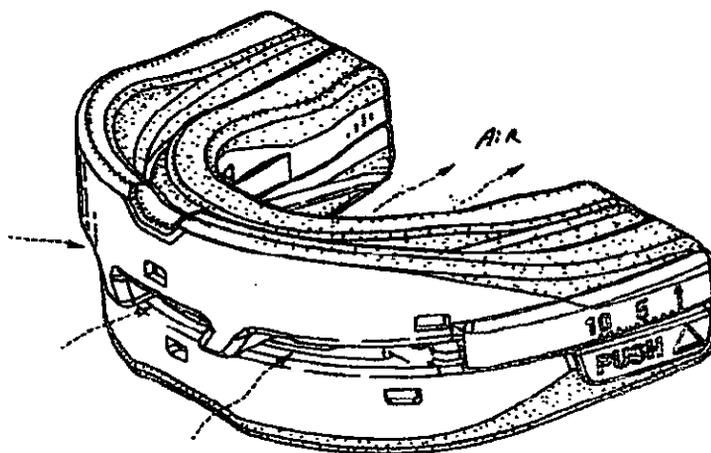
Premarket Notification

Performance Testing

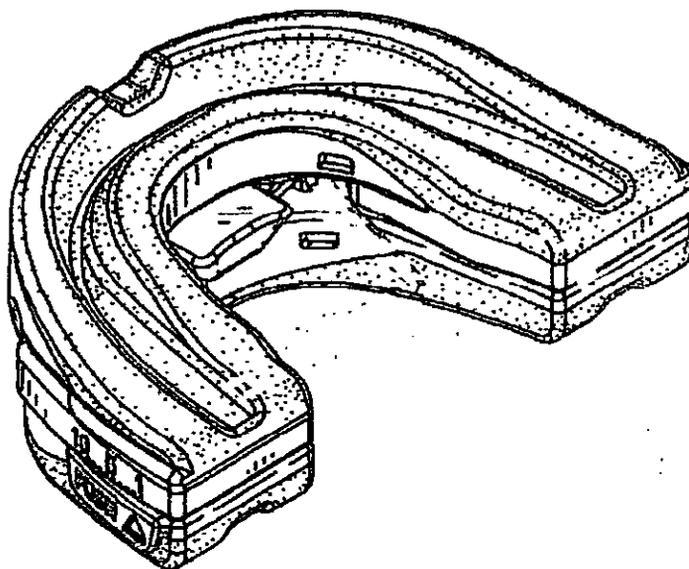
Performance testing was conducted by CIRO Design & Engineering for the Consumer Health Products SnoreRx NS 9.0 to demonstrate the integrity and suitability of the device for its intended use. The results of the testing indicate that the Consumer Health Products SnoreRx NS 9.0 C is substantially equivalent to the predicate devices and is safe and effective for its intended use.

12. Device Description

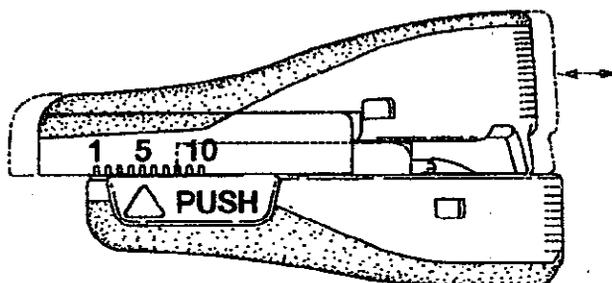
The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce or eliminate snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The common term for these types of devices is a Mandibular Adjusting Device (MAD). The device consists of two custom fabricated trays (constructed with a material to allow for customizing teeth impression) that fit separately over the upper and lower dental arches, and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep.

SnoreRx NS 9.0*Fig.*

This schematic provides a detailed description of the SnoreRx NS 9.0. The arrows in the front illustrate the airway channels that facilitate mouth breathers. The engraved word "PUSH" serves to unlock the lower tray for resetting. The gradient scale, "10-5-1" records the setting that corresponds to the relative repositioning distance selected for quick future reference.

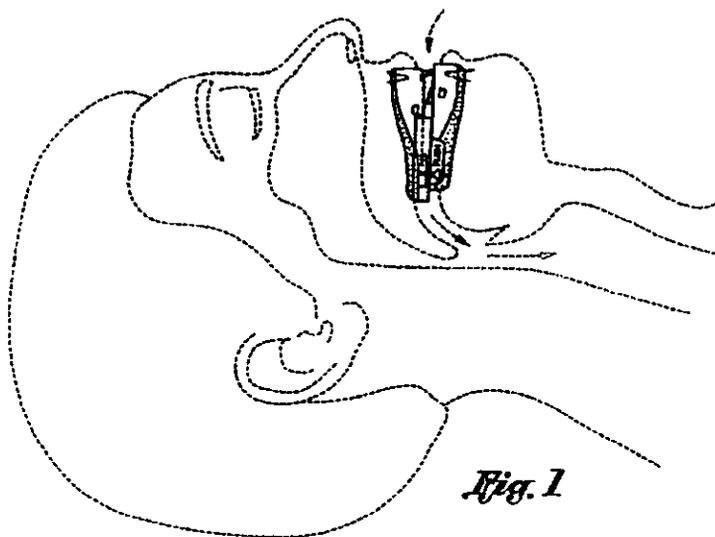
*Fig.*

The illustration noted above provides a rear view of SnoreRx NS 9.0. The upper tray, like the lower tray includes a center channel that utilizes a typical "boil and bite" method for customizing teeth impression.

*Fig. 2*

This side view schematic illustrates via the "arrow" how the lower tray may be advanced. The indicator labeled "PUSH" unlocks the upper and lower trays for micro adjustment of the device. The selected setting is then recorded on the side scale. The setting in the schematic is noted as "5".

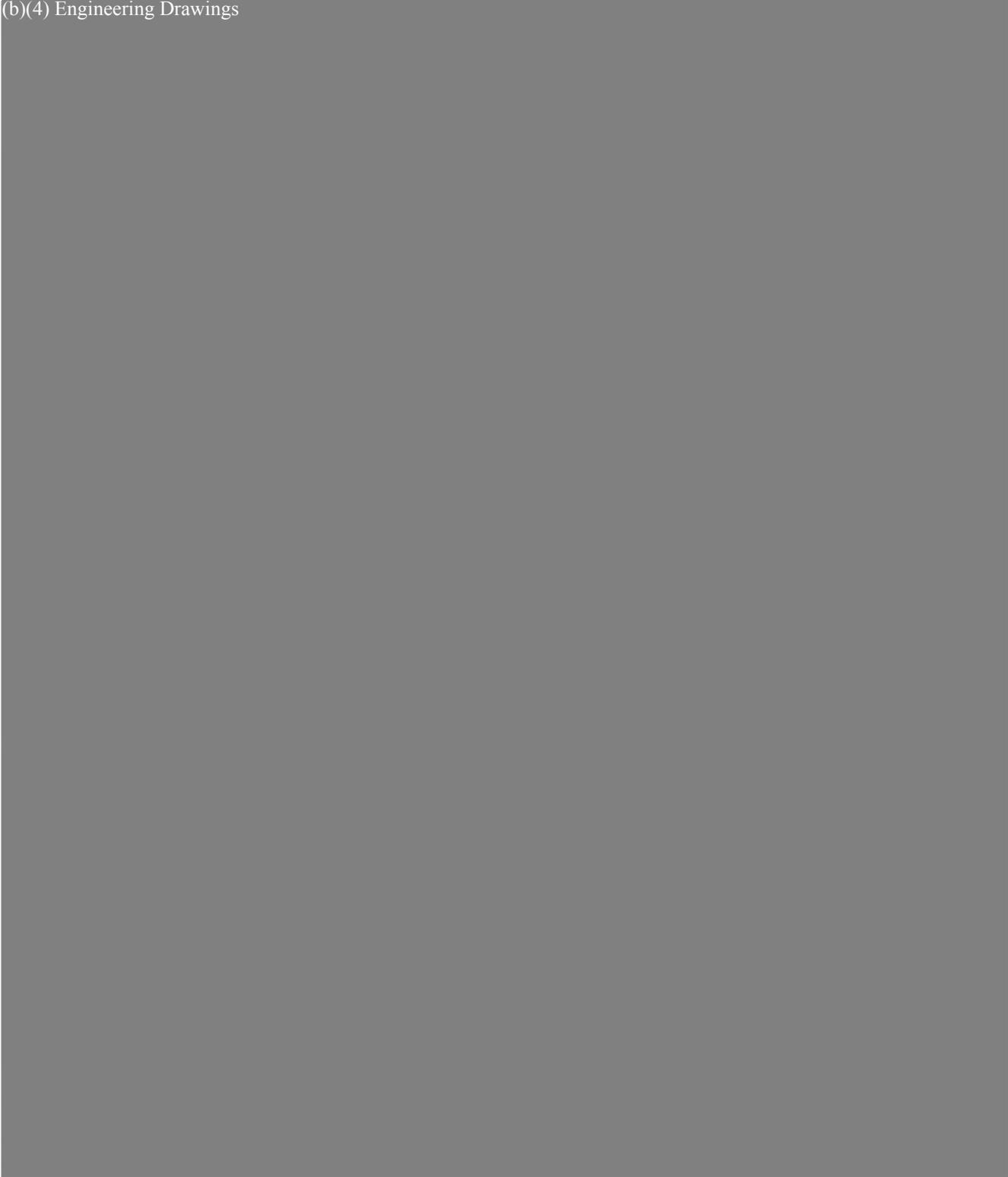
SnoreRx NS 9.0



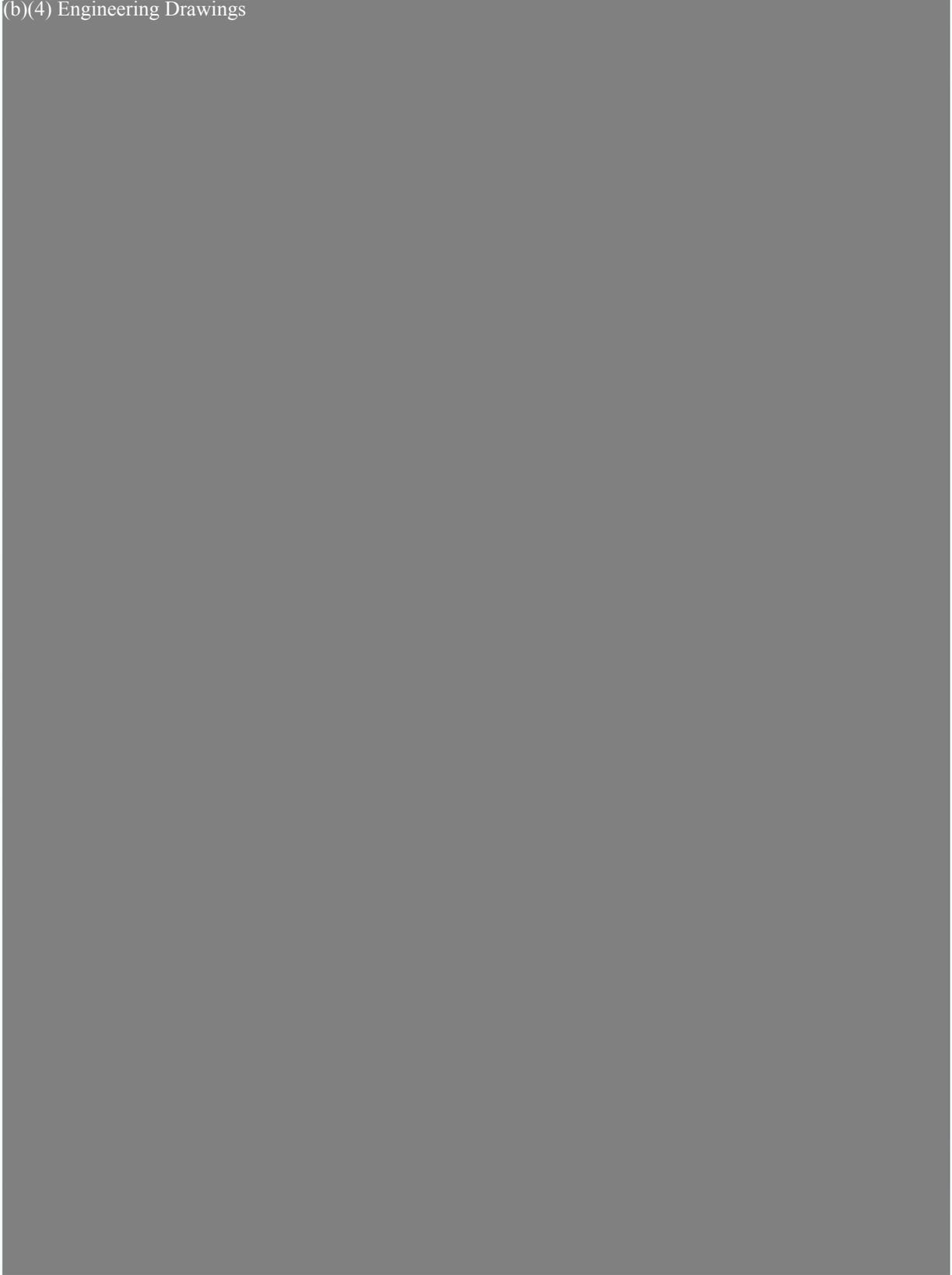
The schematic above depicts a potential patient reclined on his back wearing the SnoreRx NS 9.0. The "arrows" indicate air intake through the patient's mouth, through the SnoreRx and into the patient. It also notes a slight advancement of the lower jaw.

Dimensional information for the device is provided in the following figures

(b)(4) Engineering Drawings



(b)(4) Engineering Drawings

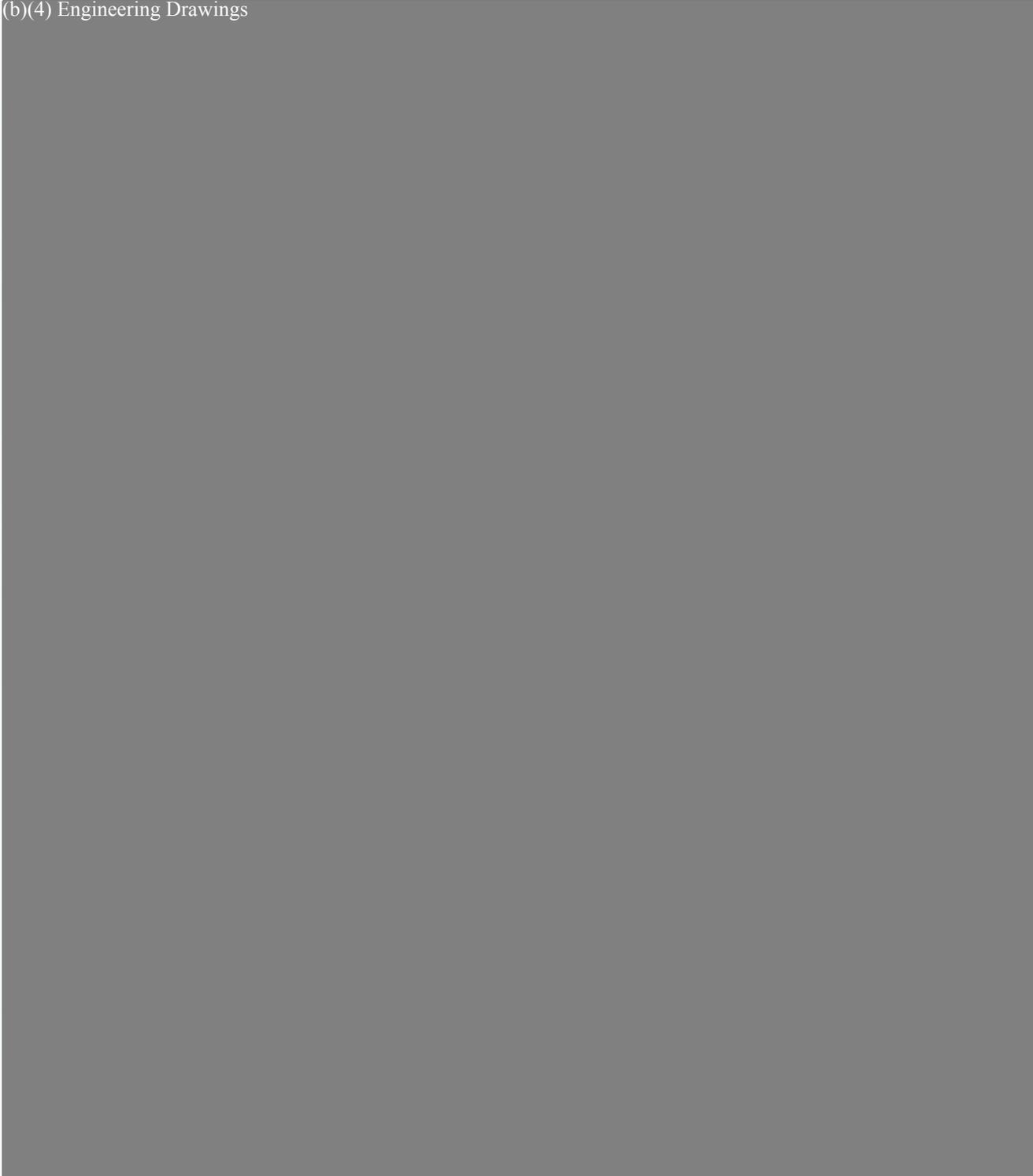


Consumer Health Products, Inc
SnoreRx NS 9.0

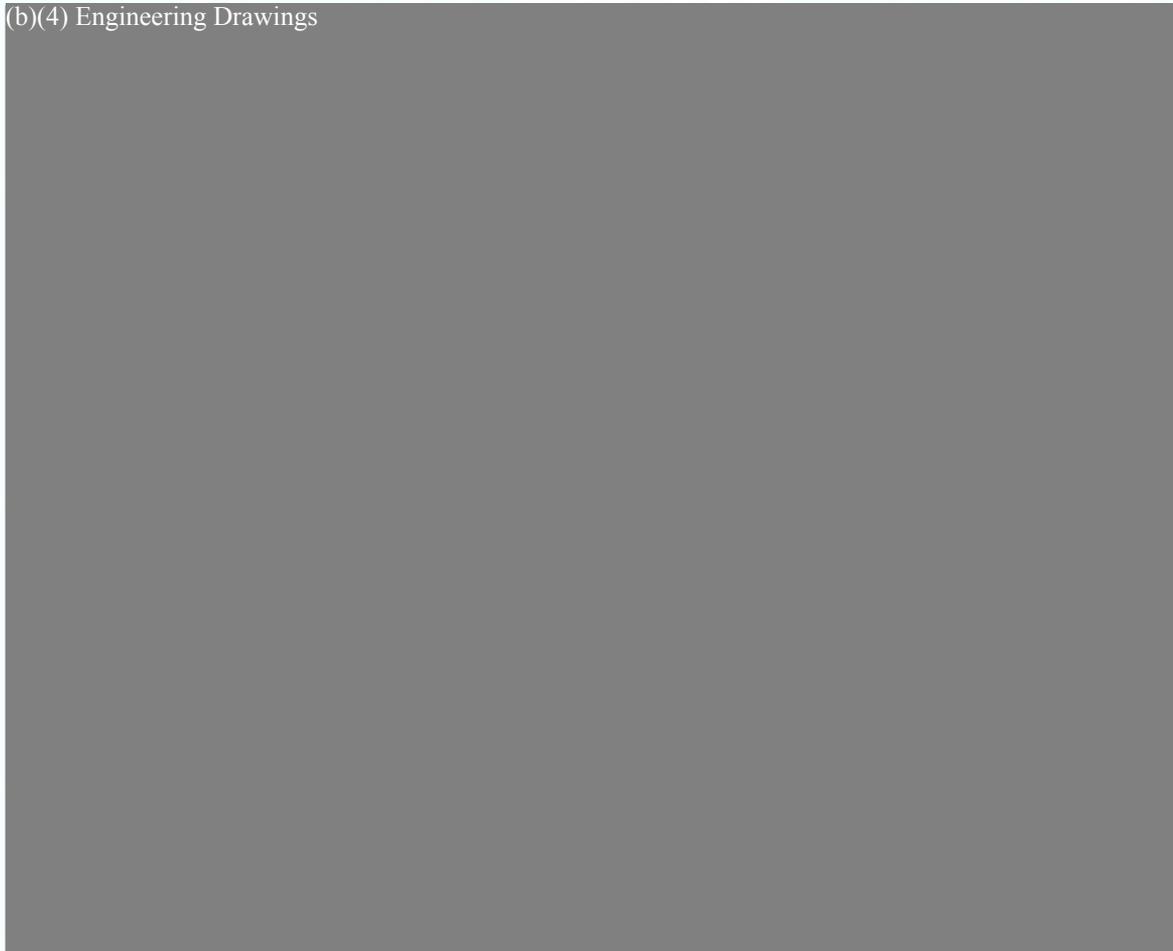
Premarket Notification

Drawings showing the two materials used

(b)(4) Engineering Drawings



(b)(4) Engineering Drawings



Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Device Construction

The Consumer Health Products SnoreRx NS 9.0 is fabricated from materials commonly used in the dental device industry and manufactured using well-known and established processes.

The tray material, Eastar Copolyester MN058 has been found to be biocompatible and is utilized in many previously cleared devices. The material is molded into the desired shape using molding processes that are validated and are accomplished without the use of mold release agents or other potential contaminants. Additionally, the impression component, Dupont ELVAX 3165 EVA has also been found to be biocompatible. This material is also molded into the desired shape using molding process that are validated and accomplished without the use of mold release agents or other potential contaminants. Subsequent to the molding operation, the EVA molded components are pressed into the trays. The EVA allows for customization of the teeth impressions.

The molding operation, the assembly of the device, and the final packaging of the device is completed in a controlled manufacturing environment utilizing documentation and procedures that are compliant with the FDA QSR.

Device Operation and Features

The SnoreRx NS 9.0 employs a "Boil & Bite" design to provide a custom impression for each patient. The SnoreRx is boiled for one minute, removed, and then cooled for 7-10 seconds. It is then placed in the patient's mouth where they will bite down will full force for 30 seconds. It is then removed and place in a bowl of ice water for thirty seconds. This acts to lock in the teeth impression.

SnoreRx NS 9.0 works by allowing either the patient, or healthcare professional, to micro adjust the upper or lower trays in 1mm increments. It locks in the desired setting, but also allows for future changes. By depressing the indicator labeled "PUSH" it unlocks the setting. By continuing to depress the button labeled "PUSH," you may then move the lower tray into the new desired position. By releasing the "PUSH" button, the new setting is locked in place.

Section 13

Substantial Equivalence Discussion

13. Substantial Equivalence Discussion

Information on these substantially equivalent devices is provided in APPENDIX 1 of this premarket notification.

The 510(k) "Substantial Equivalence" Decision-Making Process in ODE Guidance Document #K86-3, Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence (see Figure 13-1). Tables shown below compare the attributes of the predicate devices to the Consumer Health Products "SnoreRx NS 9.0". Answers to the relevant questions lead to a determination of substantial equivalence, as follows:

1. DOES THE DEVICE HAVE SAME INDICATION STATEMENTS?.....YES

The indication statements for the Consumer Health Products "SnoreRx NS 9.0" are represented by the predicate device(s), in whole or in part, as illustrated in Table 13-1 below:

Table 13-1: Comparison of Indication Statements

Consumer Health Products "SnoreRx NS 9.0"	SomnoGuard K950592	SILENT KNIGHTS VENTURES, INC Silencer K954530	KENNETH HILSEN SnoreControl K963591
The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring only.	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	Intended to alleviate snoring in patients 18 years of age or older.	The anti-snoring device is intended to alleviate or correct snoring

2. DOES NEW DEVICE HAVE THE SAME TECHNOLOGICAL CHARACTERISTICS, E.G., DESIGN, MATERIALS, ETC.?.....YES

The Consumer Health Products "SnoreRx NS 9.0" has similar technological characteristics when compared to the predicate devices (e.g. principal of operation, placement methods, etc.). The tables below illustrate the similarities and differences in technological characteristics:

Section 13**Substantial Equivalence Discussion****Comparison of Predicate Devices**

[807.92(a)(5)]

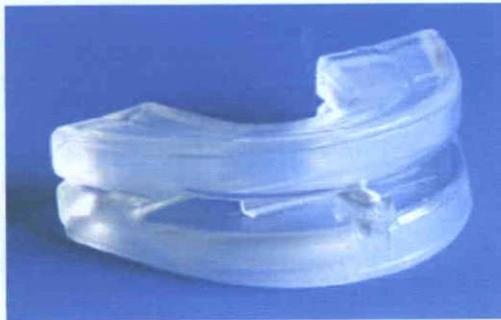
Attribute	SnoreRx	SomnoGuard	Silencer	SnoreControl
	K110564	K950592	K954530	K963591
Year FDA Cleared		2006	1995	1997
Use:				
Intended as an intraoral device	Yes	Yes	Yes	Yes
Intended to reduce or help alleviate snoring	Yes	Yes	Yes	Yes
Indicated for use with persons who snore	Yes	Yes	Yes	Yes
Indicated for single user	Yes	Yes	Yes	Yes
Indicated for use at home	Yes	Yes	Yes	Yes
Design:				
"Boil & Bite" material for fitting	Yes	Yes	Yes	Yes
Can be adjusted	Yes	Yes	Yes	Yes
Permits User to breath through mouth & nose	Yes	Yes	No	Yes
Fixed and stable retention	Yes	Yes	No	Yes
Designed with upper and lower tray	Yes	Yes	No	Yes
Custom for each user	Yes	Yes	Yes	Yes
Incorporates alignment for proper fitting	Yes	Yes	Yes	Yes
Placed in users mouth each evening	Yes	Yes	Yes	Yes
Cleaned daily	Yes	Yes	Yes	Yes
Easily removed from mouth	Yes	Yes	Yes	Yes
Sanitized when boiled	Yes	Yes	Yes	Yes
Materials:				
Non Sterile	Yes	Yes	Yes	Yes
Heat Sensitive Moldable	Yes	Yes	Yes	Yes
Health Grade Copolymer Plastic BPA FREE	Yes	Yes	Yes	Yes

DESCRIPTION OF PREDICATE DEVICES



SnoreRx NS 9.0

SnoreRx NS 9.0: is designed as a "Boil & Bite" oral appliance to treat snoring in adults only. Offers micro adjustments in 1mm increments to achieve maximum comfort and clinical effectiveness. The setting may be changed at any time and re adjusted. Future adjustments can also be made. Full airflow through two front air channels accommodates mouth breathers. A central centering 'V' channel assures proper alignment.



SomnoGuard AP

SomnoGuard AP: Two part mandibular adjustable oral appliance with thermoplastic body to treat snoring. A Health grade polycarbonate plastic shell accommodates for the teeth impression after boiling. Offers micro adjustability. Front offers full air flow for mouth breathers. Features fixed and stable retention and proper alignment.



Silencer

Silencer: A fully adjustable oral appliance for the treatment of snoring. It is capable of 10mm of adjustment. It is made from Health grade plastic that offers excellent fixation. Front air channel allows for mouth breathers.



Snore Control

Snore Control: Consists of two Health grade thermoplastic trays with a velcro like attachments on the occlusal surfaces of both. It is retained by friction grip to the teeth. This provides full adjustment over a wide range by the patient. A front air channel provides full air flow for mouth breathers

PERFORMANCE DATA EQUIVALENCE

Performance Standard	SnoreRx	SomnoGuard	Silencer	SnoreControl
Design - provides adequate air channel	two in front	central channel	front channel	front channel
Design - incorporates alignment feature	Yes	Yes	Yes	Yes
Design - setting may be changed and reset	Yes	Yes - screw	Yes - Plate	Yes - Velcro
Design - Employs two trays - upper / lower	Yes	Yes	Yes	Yes
Offers custom thermal fit	Yes	Yes	Yes	Yes
Locking mechanism to maintain advancement	Yes	Yes -	Yes - plate	Yes - Velcro
Ability to micro adjust advancement	Yes	Bolt/screw	Yes	Yes
Material - Health grade thermoplastic	Yes	Yes	Yes	Yes

3. ARE THE DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH TO ENSURE EQUIVALENCE?..... YES

The descriptive characteristics of intraoral devices for snoring are reasonably precise and provide adequate information to determine equivalence. The Consumer Health Products SnoreRx NS 9.0 and the identified predicates are all intraoral devices used at night to reduce or eliminate snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The devices typically consist of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus these devices, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep.

4. ARE PERFORMANCE DATA AVAILABLE TO ASSESS EQUIVALENCE?..... YES

Performance data assessing the safety and effectiveness of the Consumer Health Products "SnoreRx NS 9.0" are included in this premarket notification submission to adequately assess and report on the device performance. Performance data was based on well-known characteristics common to the predicate devices.

5. DOES THE PERFORMANCE DATA DEMONSTRATE EQUIVALENCE? YES

The performance data submitted in this premarket notification clearly demonstrates equivalence between the Consumer Health Products SnoreRx NS 9.0 and the predicate device.

6. REASON FOR PREMARKET NOTIFICATION?

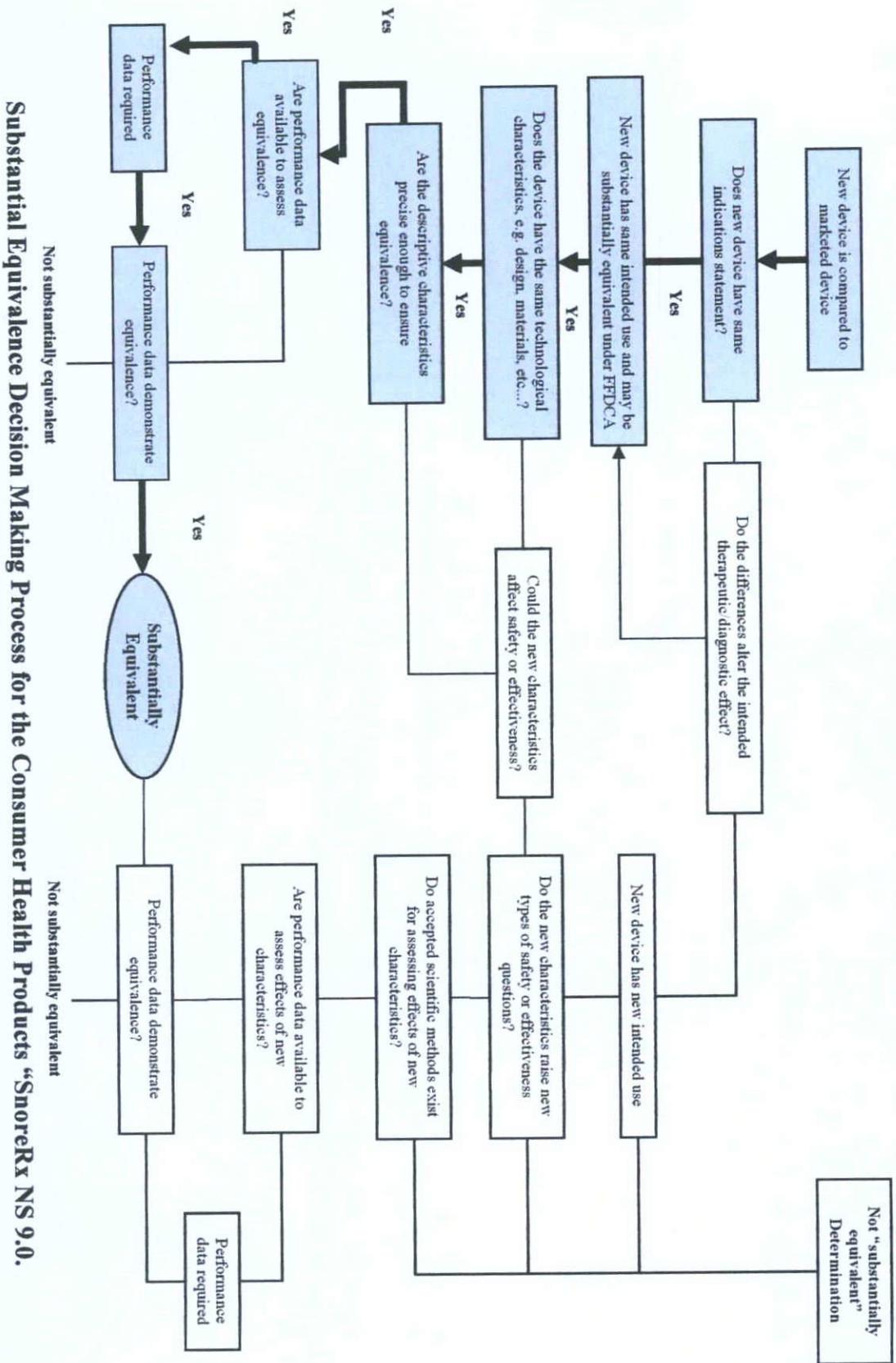
Commercial distribution of a new substantially equivalent device.

CONCLUSION:

The Consumer Health Products "SnoreRx NS 9.0" and the referenced predicates are all intended for use as an intraoral device to reduce or eliminate snoring. The Consumer Health Products "SnoreRx NS 9.0" and the predicate devices all provide a method for advancing the lower jaw. Consumer Health Products "SnoreRx NS 9.0" and the predicates all have plastic bite trays and a predetermined mechanical action that provide for the clinical effect. The Consumer Health Products "SnoreRx NS 9.0" is substantially equivalent, in terms of intended use, principle of operation, technological characteristics, and performance characteristics to the listed predicates.

Section 13

Substantial Equivalence Discussion



Substantial Equivalence Decision Making Process for the Consumer Health Products "SnoreRx NS 9.0."

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Section 14

Proposed Labeling

14. Proposed Labeling

The following sections contain the proposed labeling (Section 14.1) and proposed instructions for use (Section 14.2)

14.1 Primary Labeling

DRAFT BOX LABEL

SnoreRx NS 9.0

You deserve a good night's rest
WE GUARANTEE IT!

Caution: Federal law restricts this device to sale on or by order of a physician or an appropriately licensed practitioner

"SnoreRx NS 9.0 is endorsed as a proven clinical treatment for snoring."

QAOSA 2011
Meets & Exceeds
Recommended Standards

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

14.2 Draft Instructions for use

SNORERX
NS 9.0



INSTRUCTIONS FOR CARE & USE
[21 CFR 80787(E)]

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN, OR AN APPROPRIATE LICENSED PRACTITIONER

SnoreRx NS 9.0 is an intraoral appliance designed to reduce or eliminate snoring by keeping your airway open. It does not treat any Health or clinical condition. If you believe you may have a Health issue such as sleep apnea, you should consult your healthcare professional immediately.

CONTRAINDICATIONS

The SnoreRx NS 9.0 is contraindicated in patients who:

- Patients with sleep apnea
- Patients under the age of 18
- Patients with a history of TMD, temporomandibular disorder
- Patients who have had teeth implants within the past year
- Patients who wear dentures
- Patients with loose teeth, abscesses, or severe periodontal gum disease
- Patients undergoing orthodontic treatment
- Patients with chronic asthma, emphysema, or any respiratory disorder

WARNINGS

The use of the SnoreRx NS 9.0 may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Excessive salivation

PRECAUTIONS

Dentists should consider the Health history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

HOW TO PREPARE FOR FITTING

1. You should first brush your teeth
2. Next floss to remove any remaining food particles

PREPARING FOR A CUSTOM FIT

You will need the following:

- Timer with second hand
- A small pot for heating two quarts of boiling water
- A towel
- A small bowl of ice water
- A spatula, or tongs

FITTING PROTOCOL

Fitting SnoreRx NS 9.0 is simple and straightforward when these step by step directions noted below are followed.

1. Boil two quarts of water, remove the pot from the stove and turn off the stove. Do not leave boiling water unattended.
2. Using the spatula or tongs place the SnoreRx NS 9.0 in the boiled water for precisely one minute. Use the spatula, or tongs to hold the SnoreRx submerged in the water.
3. Let the SnoreRx cool for 7-10 seconds, then:
 - Place it in your mouth
 - Bite down firmly for thirty seconds
 - Remove from your mouth
 - Place in a bowl of ice water for one minute. **DONE!**

SnoreRx NS 9.0 works best if you have made a deep impression of your teeth. If you have not made the best impression of your teeth, repeat steps 1,2,3.

BEFORE YOU USE SNORERX NS 9.0

We recommend that you wear your SnoreRx NS 9.0 for 1-3 hours for each of the preceding two days. This helps acclimate your mouth to wearing it. Be advised it normally takes 4-7 days for most users to achieve a level of comfort to wearing the SnoreRx NS 9.0. You certainly may take it out if you are awakened by wearing it initially.

NOTICE

Your SnoreRx is now thermally custom fitted to you. No one else should attempt to use it.

CAUTION:

It is not normal to experience severe, sharp pain or for your jaw to suddenly become more limited in its ability to open, or experience clicking, or popping sounds when you move your jaw. These symptoms may be an indication of temporomandibular disorder, or TMD. If your snoring becomes worse, or you experience difficulty breathing while using SnoreRx NS 9.0 **DISCONTINUE USE IMMEDIATELY**. If these symptoms persist, contact your dentist, or physician. Contact the company for a full refund.

CARE OF YOUR SNORERX NS 9.0

Be sure to store your SnoreRx in a cool dry place. Clean with a toothbrush, or ultrasonic cleaner after each use. Do not use harsh chemicals like bleach, or ammonia.

15. Sterilization and Shelf Life

Sterility

This section does not apply. The SnoreRx NS 9.0 is provided non-sterile.

Shelf Life

The shelf life of the product has been established based on the package integrity testing performed to confirm that the packaging protects the product from damage during distribution and the functional performance of the device materials.

16. Biocompatibility**Applied Standard**

ISO 10993 along with the USP was used as a standard for biocompatibility compliance. ISO 10993-1 was used to determine the appropriate categorization of the device based on the nature and duration of contact with the body. The Blue Book Memorandum G95-1 entitled "Use of International Standard ISO- 10993, Biological Evaluation of Health Devices Part 1: Evaluation and Testing" and Table 1 of ISO 10993-1 were used as tools for the initial evaluation of tests for consideration.

Categorization of the deviceIntended Use

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction and/or alleviation of snoring.

Nature and duration of body contact

The SnoreRx NS 9.0 is a surface device that contacts intraoral (i.e. mucosal, gingival, and palatal) surfaces for prolonged contact.

Section 16

Biocompatibility

Test Selection

Based on the device categorization outlined above, the nature of the material contact and the guidance given in ISO 10993-1 as well as FDA Blue Book memorandum G-95, the minimum tests deemed appropriate for the device materials were selected as shown in the table below:

Table 16-1: Materials List / Test Selection

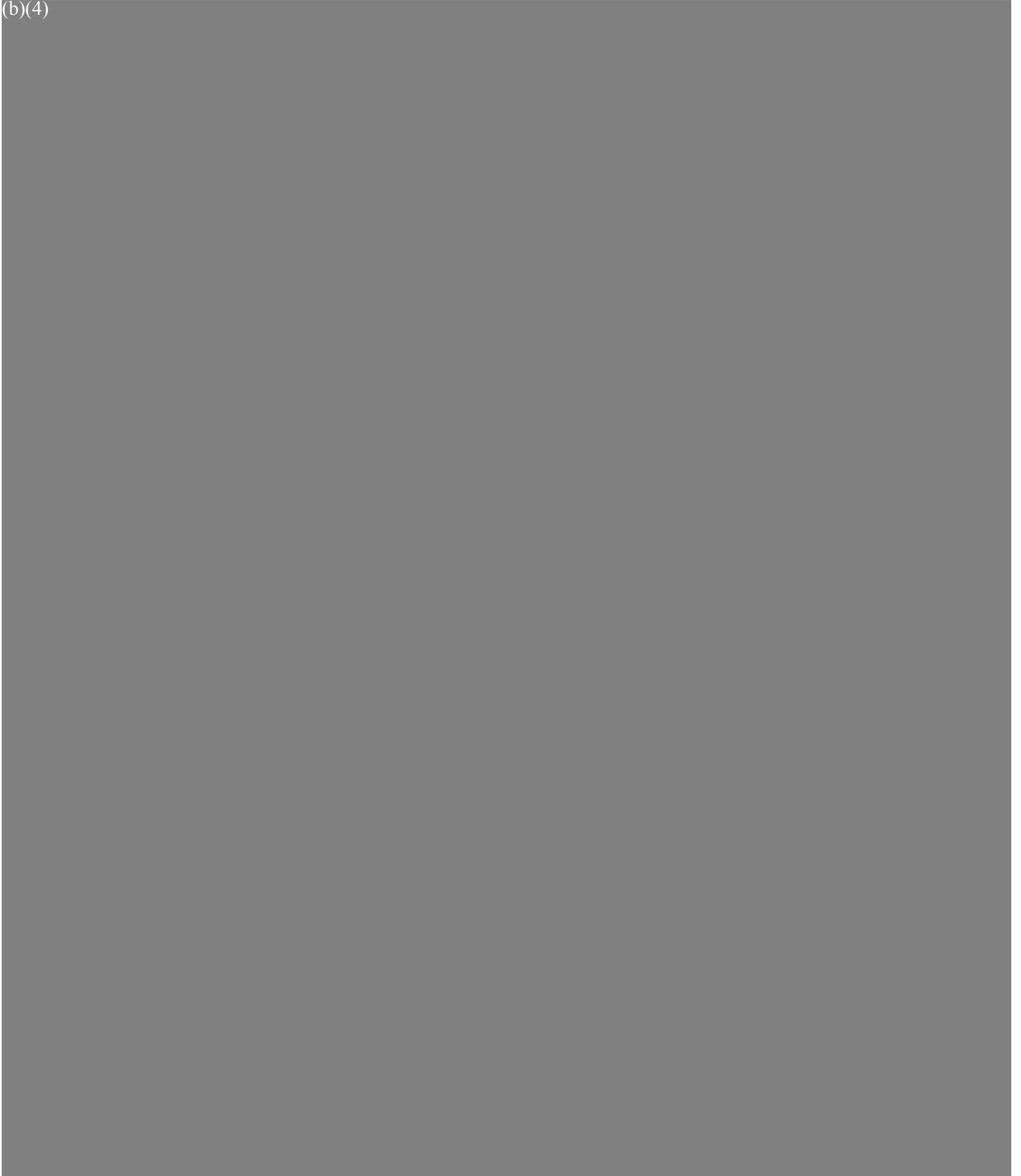
Material	Component/ Nature of contact	Test Selection
(b)(4)	Surface (mucosal) contact Prolonged tissue contact for less than 30 days.	Cytotoxicity- MEM Elution Irritation- Intracutaneous Sensitization- Guinea Pig Maximization
	Surface (mucosal) contact Prolonged tissue contact for less than 30 days	Systemic toxicity Intracutaneous toxicity Intramuscular implantation

(b)(4)

All studies were conducted in compliance with the current FDA 21 CFR, Part 58 - Good Laboratory Practice

Results

(b)(4)



Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

227

(b)(4)



Conclusion

The results from all tests indicate that the materials utilized to fabricate the Consumer Health Products SnoreRx NS 9.0 is non-toxic, and non-irritating and therefore biocompatible for its intended use.

(b) INFORMATION
Data Sheet
MSDS
Biocompatibility Test Results from (b) (4)

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

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Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

(b) (4) **INFORMATION**
Data Sheet
MSDS
EVA Biocompatibility Information

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

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Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Section 17

Software

17. Software

This section does not apply.

Section 18

**Electromagnetic Compatibility
And Electrical Safety**

18. *Electromagnetic Compatibility and Electrical Safety*

This section does not apply.

19. Performance Testing

Bench testing was performed on the Consumer Health Products SnoreRx NS 9.0 to support the substantial equivalence of the device to the identified predicates.

SnoreRx NS 9.0 samples were tested to establish performance of key design features to substantiate equivalence. All test units were representative of finished devices. The key functions and performance criteria were established based on an approved Risk Analysis conducted on the device design.

(b)(4) Test Data



Conclusion

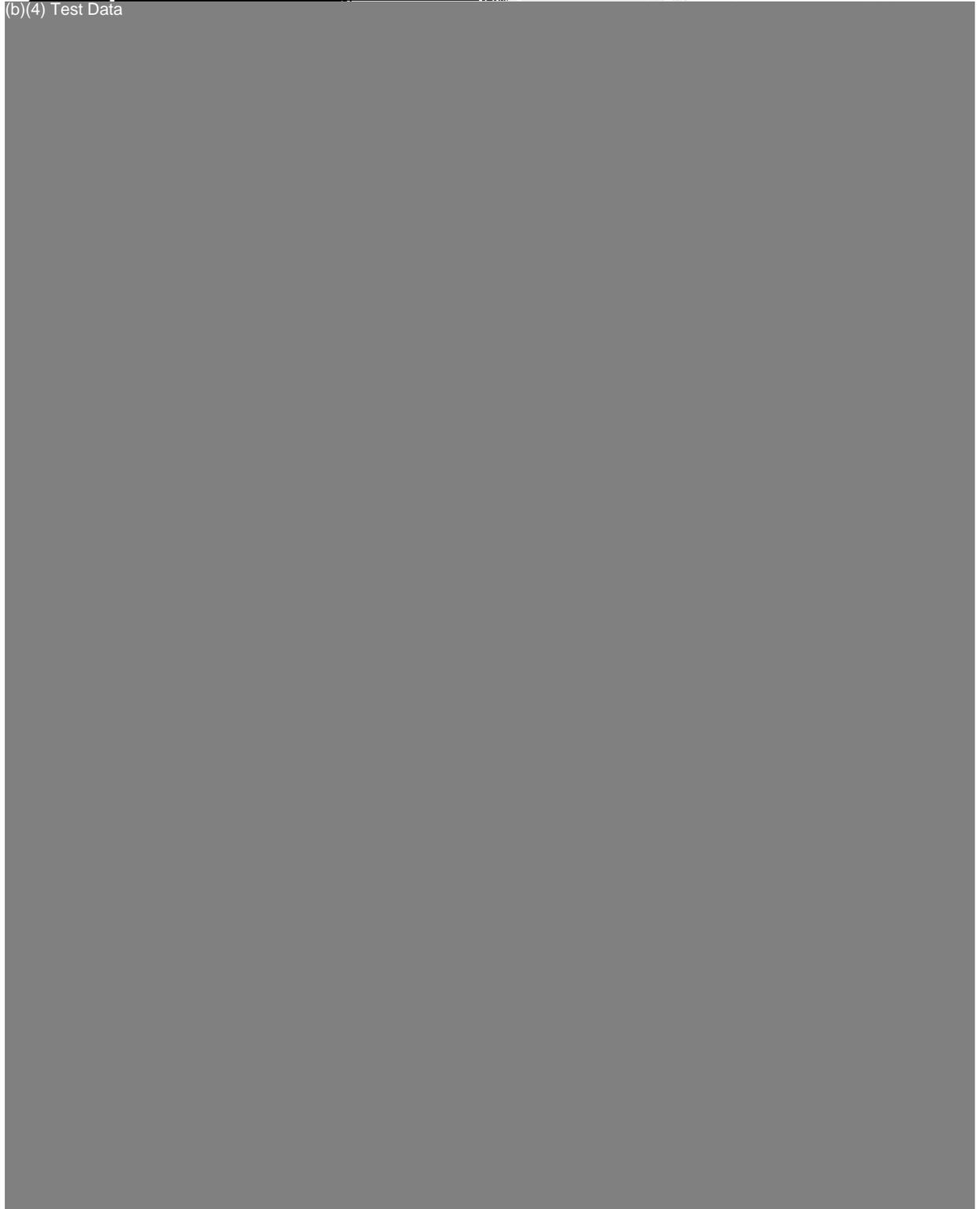
All test units satisfied the established acceptance criteria. The results of the testing support the equivalence of the Consumer Health Products SnoreRx NS 9.0 to the predicate devices

PERFORMANCE TESTING

MouthGuard NS 9.0

Control #	Test Protocol	Within Specifications	Outside Specifications	Passed	Failed
-----------	---------------	-----------------------	------------------------	--------	--------

(b)(4) Test Data



Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

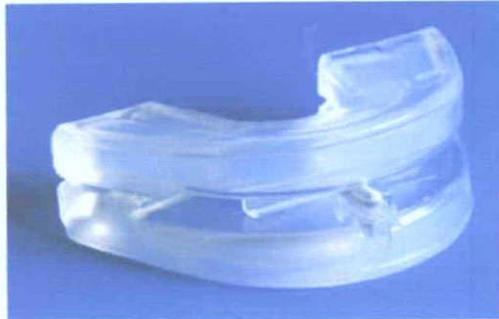
20. Performance Testing- Animals

This section does not apply.

21. Clinical Data

This section does not apply.

**SomnoGuard
(K050592)**



SomnoGuard : Two part mandibular adjustable oral appliance with thermoplastic body to treat snoring. A Health grade polycarbonate plastic shell accommodates for the teeth impression after boiling. Offers micro adjustability. Front offers full air flow for mouth breathers. Features fixed and stable retention and proper alignment.



K050592

Level 3, 20 Clarke Street
Crows Nest, NSW 2085
Australia

Tel: +61 2 9439 9890
Fax: +61 2 9439 9892

www.somnomed.com.au

510(k) Summary

Contact Person: Elaine Duncan
Paladin Medical Inc.
PO Box 560
Stillwater MN 55082
Tel: (715) 549 6035
Fax: (715) 549 5380

JUL 12 2005

Brand Name: SOMNOMED MAS RXA
Common Name: Mandibular advancement device
Classification Name: Device, anti-snoring (21CFR872.5570)
Product Code: LRK
Predicate Device: MDSA K042161
Date Prepared: 3 March 2005

Description Of The Device: The Somnomed MAS RxA is an intraoral device used for treating Snoring and Sleep Apnea. It consists of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable lugs. The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep. The device is custom made for each patient and has the 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: The SomnoMed MAS RxA is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Summary of Equivalence: The Somnomed MAS RxA is considered to be substantially equivalent to the Bird MDSA device. Both the Somnomed MAS RxA and the MDSA are prescription Custom Made titratable mandibular repositioning devices for the dental treatment of patients suffering snoring and mild to moderate obstructive sleep apnea.

The technical designs and manufacture of the two devices are almost identical, being composed of custom fitted acrylic trays which fit onto the upper and lower teeth and which are positioned in relation to each other by an adjustable mechanism. The only design difference is in the nature of the adjustable mechanisms in the two devices. The MDSA device achieves mandibular advancement by means of a locking clasp placed at the front centro of the two acrylic trays, whereas the Somnomed RxA uses interlocking lugs and wings placed on the sides of the trays. The dental acrylic, adjustment screws and ball clasps used to manufacture the Somnomed MAS RxA have all been granted prior 510(k) approval for use in manufacture of dental appliances

A risk assessment concluded that there were no new safety concerns raised by the design of the Somnomed MAS RxA.

7 — 1 (amended)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2 2005

Somnomed Limited
C/O Ms. Elaine Duncan
Paladin Medical Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K050592
Trade/Device Name: MAS RxA
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: LRK
Dated: June 9, 2005
Received: June 15, 2005

Dear Ms. Duncan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

265

Appendix 1

Predicate Device Information

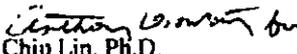
Page 2 – Ms. Duncan

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA 510(k) – K050592 – Response to Reviewers Questions: Somnomed MAS RxA

Indications For Use

510(k) Number (if known): K050592

Device Name: MAS RxA

Indications For Use:

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

Prescription Use X AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (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)


 (Division Sign-Off)
 Division of Anesthesiology, General Hospital,
 Infection Control, Dental Devices
 510(k) Number K050592

5-1 (Amended)

**Silencer
(K954530)**

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

268

Appendix 1

Predicate Device Information

510(k) Premarket Notification



[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [Classification](#) | [Standards](#)
[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#)

[New Search](#)

[Back To Search Results](#)

Device Classification Name	<u>Device, Anti-Snoring</u>
510(K) Number	K954530
Device Name	THE SILENCER
Applicant	SILENT KNIGHTS VENTURES, INC. 1050-1188 West Georgia St. Vancouver,
Contact	L. Wayne Halstrom
Regulation Number	<u>872.5570</u>
Classification Product Code	<u>LRK</u>
Date Received	09/29/1995
Decision Date	10/30/1995
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Type	Traditional
Reviewed By Third Party	No
Expedited Review	

SnoreControl
(K963591)

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

270



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenneth Hilsen
Mr. Stephen E. Feldman
C/O Law Office of Stephen E. Feldman, P.C.
12 East 41st Street
New York, New York 10017

JAN - 9 1998

Re: K963591
Trade Name: Snoring Control Device
Regulatory Class: Unclassified
Product Code: LRK
Dated: October 17, 1997
Received: October 21, 1997

Dear Mr. Hilsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

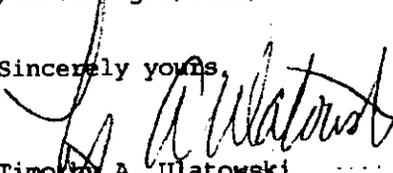
Page 2 - Mr. Hilsen

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT 5

Page 1 of 1

510(k) Number (if known): Not Known

Device Name: Hilsen Anti-Snoring Device

Indications For Use:

The Anti-Snoring Device is intended to alleviate or correct snoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Purson
(Division Sign-Off)
Division of Device, Infection Control,
and General Hospital Devices
510(k) Number K963591

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

END OF SUBMISSION

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification



COVER SHEET MEMORANDUM

1: Reviewer Name Sheena A. Green
Subject: 510(k) Number K112205/32
10: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist. http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacorn/morechoices/fdaforms/FDA-3654.pdf).		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		✓	✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
Does this device include Pediatric Patients age<=21			✓

Neonate/Newborn (Birth to 28 days)		✓
Infant (29 days -< 2 years old)		✓
Child (2 years -< 12 years old)		✓
Adolescent (12 years -< 18 years old)		✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		✓
Transitional Adolescent B (18 ≤ 21; No special considerations compared to adults ⇒ 21 years old)	✓	
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	✓

Regulation Number: 21CFR 872.5570 Class*: II Product Code: LRK
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: *[Signature]* *[Signature]* 11/14/11
 (Branch Chief) (Branch Code) (Date)

Final Review: *[Signature]* 11/15/11
 (Division Director) (Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

510(k) Memorandum

TO: The Record

FROM: Sheena A. Green
ODE/DAGID/DEDB

DATE: November 14, 2011

SUBJECT: *SnoreRX NS 9.0 (K112205/S2)*

CONTACT: Gary Mocnik
Regulatory Consultant
Aliso Viejo, CA 92656
Phone: (949)433-0413
Fax: (949)831-9944
Email: gmocnik@cox.net

RECOMMENDATION: Substantially Equivalent (SE)

Purpose and Submission Summary:

Gary Mocnik & Associates of Aliso Viejo, CA has submitted a pre-market notification (510(k)) on behalf of Consumer Health Products, Inc of Laguna Niguel, CA to introduce the *SnoreRX NS 9.0* into interstate commerce. *SnoreRX NS 9.0* would be regulated as a prescription Class II medical device, and would be classified under 21 CFR 872.5570, as an Intraoral device for snoring and an intraoral device for snoring and obstructive sleep apnea, product code LRK.

The sponsor claims substantial equivalence to the following predicates:

- Snore Guard(K050592)
- Silencer (K954530)
- Snore Control (K963591)
- Pure Sleep now known as SnoreMaster (K954128)

The submission claims conformity to the following standard and/or guidance document:

- ISO 10993-1:2003 Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing
- ISO 10993-5:2003 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity
- ISO 10993-10:2003 Biological Evaluation of Medical Devices – Part 10 Intracutaneous

7

- Irritation Testing
- ISO 10993-11:2003 Biological Evaluation of Medical Devices – Part 11 Sensitization testing
 - Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA, November 12, 2002.
 - FDA Blue Book memorandum G-95

Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) <u>Statement</u>	X		
Standards Form		X	

510(k) Summary / 510(k) Statement:

The sponsor has provided a 510(k) summary in the original submission.

		YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)				
Clearly labeled "510(k) Summary"		X		
Submitter's name, address, phone #, a contact person		X		
Date the summary was prepared		X		
The name of the device/trade name/common name/classification name		X		
An identification of the legally marketed Predicate		X		
Description of the subject device		X		
Statement of intended use(identical to indications for use)		X		
Technological characteristics	if same, a summary of comparison of technological characters	X		
	If different, a summary of how do they compare to the Predicate	X		
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	X		
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination 			X
	Conclusion that data demonstrate SE	X		

	YES	NO	N/A
Required Elements for 510(k) Statement (21 CFR 807.93)			
Signed verbatim statement			X

Indications for Use:

“The Consumer Health Products “SnoreRX NS 9.0” is intended for use on adult patients 18 years or older as an aid for the reduction of snoring.”

Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are “cleaning” instructions included for the end user?	X		

SnoreRX NS 9.0 is an intraoral device that is used at night to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface causes *the SnoreRX NS 9.0* to function as a mandibular anterior repositioner. The device employs a “boil & bite” design to provide custom impression for each patient. The *SnoreRX NS 9.0* is boiled for 1 minute, removed and then cooled for 7-10 seconds. It is then placed in the patient’s mouth where they will bite down full force for 30 seconds. The device is then removed and placed in a bowl of ice water for 30 seconds which locks in the teeth impression.

The submission states that *SnoreRX NS 9.0* works by allowing the user to adjust the upper or lower trays in 1 mm increments. It locks in the desired setting but also allows for future changes. The device has a “PUSH” button feature that unlocks the setting. By continuing to depress the “PUSH” button, the user is able to move the lower tray into the new desired position and by releasing the “PUSH” button, the new setting is locked in place.

(b)(4)



Predicate Device Comparison

The sponsor claims substantial equivalence to the following predicates: Snore Guard (K050592), Silencer (K954530), and Snore Control (K963591)

The 510(k) number above referenced for the Snore Guard does not match up to what is listed in IMAGE. Therefore, it was requested in the first AI letter that the sponsor to clarify the correct 510(k) number for the Snore Guard device. In S001, the sponsor identified the correct 510(k) number for the Snore Guard as K103004. In addition, in S001 the sponsor identified the Snore Master renamed Pure Sleep (K954128) as an additional predicate.

The subject device was compared to the other two predicates K954530 and K963591. The intended uses of the subject device and predicate devices are similar in that they are all to reduce snoring and are for patients 18 years or older.

The designs of the subject and predicate devices are similar. All devices consist of two parts: upper and lower trays made of a hard acrylic. The trays of the subject device are made from ELVAX 3615 while the trays of the Silencer are made from ELVAX 40. All devices allow mandibular advancement of the patient's jaw. There are differences in the type of mechanism that engages the two trays. The subject device is engaged by a "PUSH" button while the Silencer is engaged by a Halstrom Hinge and clasps. In addition, the labeling of these devices is similar in that they all include similar contra-indications, warnings, and precautions.

Labeling

Proposed labelling for the *SnoreRX NS 9.0* was provided in section 14 of the original submission. The proposed labeling includes a representation of the device label and a draft of the instructions for use manual. The draft of the device label include the device name, the required prescription statement, and a claim that states that the "SnoreRX NS 9.0 is endorsed as a proven clinical treatment for snoring." To support the claim above, the sponsor was asked to provide a few clinical cases. In response in S001, the sponsor removed the claim from the label. Response is acceptable. In addition, the label in the original submission was incomplete. It does not include the company's info such as name, address, etc. Therefore, in the first AI letter the sponsor was asked to revise their label accordingly. A revised label was provided in supplement one that is complete and acceptable.

The draft of the instructions for use manual includes the following: device name, prescription statement, device description, contra-indications, warnings, precautions, info on to prepare for fitting of the device, fitting protocol, cautions, and info on care of device.

It appears from the instructions for use in the original submission that both the patient and dentist fit this device. Typically, these types of devices are fitted by the dentist in his or her office; therefore it was recommended that the sponsor remove instructions that instruct the patient to fit the device and provide specific instructions for the dentist on how to prepare and fit the device. In addition, it was recommended that the sponsor provide separate patient instructions on how to care and store their device. The sponsor responded in S001 identifying a predicate device that was cleared in '95 that included instructions where it seems like the patient was involved in the fitting of the device. However, base on the Agency's knowledge about these type of these devices and current standard practices it is recommended that each sponsor provide both separate instructions for the dentist on how to fit the device etc and for the patient on how to

sponsor was asked in the first AI letter to clarify whether biocompatibility testing was performed on the final device and if so full test reports must be provided for review. Alternatively, the sponsor may identify a predicate that uses the same materials (with exact chemical compositions) with the same intended uses as the ones identified in this device.

In response, the sponsor identified predicate devices that utilize the same material composition of the materials used in the subject device. Such predicate devices include Snore Master now known as Pure Sleep (K954128). In addition, to support the biocompatibility claim the sponsor provided comparative testing to confirm the based on analytical chemistry evaluations (Infrared Spectroscopy abs Differential Scanning Calorimetry) the materials of the subject device and the listed predicate device share equivalent chemical compositions. The colorants identified in the subject device are (b)(4). To support the use of the colorants above the sponsor provided a supporting document (letter) from the supplier that states that these colorants are safe for use; however this does not adequately address the concern that with the addition of the colorants there maybe a change in the biocompatibility properties of the device. Also, the analytical chemistry evaluation testing provided appears to be incomplete and difficult to read. Therefore the sponsor was asked in the second AI letter to provide clear and complete reports of the analytical chemistry tested performed on their device or alternatively provide a signed biocompatibility certification that states that *"The combination of raw materials that make up the final product {device name} is identical to the finished products {predicates}. Therefore it can be concluded that the {device name} share the same biocompatibility with {predicate devices}."* In S002, the sponsor decided to remove all colorants from the device and provided a signed biocompatibility certification stating that all the materials that make up this device is identical to the materials that make up the predicate device Pure Sleep. This response addresses all biocompatibility concerns associated with this device.

Software

This device does not utilize software; therefore this section is not applicable.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

No electrical components are contained in the *SnoreRX NS 9.0*.

Performance Testing – Bench

The sponsor notes in section 19 that bench testing was conducted on the *SnoreRX NS 9.0* and samples of the device were tested to establish performance of key design features to substantiate equivalence. It is stated that all samples tested were representatives of finished devices. The tests conducted included an approved Risk Analysis, visual inspection, engineering and failure analysis, and a dimensional analysis.

The objective of the visual inspection was to verify that the device was free from any sharp edges that would result in harm of the patient. The purpose of the engineering and failure analysis was to verify that the device integrity was maintained throughout the evaluation. The dimensions of the airway channels of the device were studied during the dimensional analysis. This test was to assure that there is adequate airflow to accommodate full mouth breathing during sleep.

In the original submission summaries of the above tests were provided rather than the actual test reports. In addition, it was not clear on how the acceptance criteria for these tests were defined. It was recommended in the first AI letter that the sponsor provide full test reports for the bench tests above performed on their device and to clarify how the acceptance criteria for each test were established. In response, in S001 full test reports were provided and the acceptance criteria were defined by the predicate devices' specifications. The results of the Risk Analysis, visual inspection, and a dimensional analysis tests do not support the performance of this device but rather the appearance of the device. To address the concern that there may be insufficient space for air to flow through the patient's mouth to accommodate full mouth breathing during sleep the sponsor provided dimensional cross sections between the subject device and Pure Sleep (K954128). It was not clear from the information provided in S001 how some of the referenced measurements were obtained. The sponsor was asked in the second AI letter to provide a thorough test report or alternatively provide some clinical cases that demonstrate successful use of this device. In S002, sponsor provided clear description and result of the measurement test provided on their device. Results of the test show that the total airway dimension of the subject device is 86 mm² while that of the predicate was 67 mm². These results demonstrated that the SnoreRX device meets and/or exceeded the airflow capabilities of the predicate device Pure Sleep because the dimensional airway of the subject device is larger than that of Pure Sleep. It can be concluded from the data above that all concerns about there being insufficient space for air flow through the patient's mouth while using the subject device has been adequately addressed.

Performance Testing – Animal

No animal test results are required to determine substantial equivalence of these types of devices.

Performance Testing – Clinical

No clinical data was provided in the original submission; however the sponsor stated on the draft of their device label in the original submission that "SnoreRX NS 9.0 is endorsed as a proven clinical treatment for snoring." Sponsor was asked to justify such claim with the appropriate data or alternatively remove it. In response, the sponsor revised their device label to remove the above claim.

Substantial Equivalence Discussion

	YES	NO	
1. Same Indication Statement?		X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

¹ The Indications for the subject device and the predicate devices are not identical; however they share similar intended uses in that the devices are used to treat snoring and/or mild to moderate OSA.

² The differences in design of the devices do not alter the effect or raise new issues of safety because the design of this device is not unique and has been cleared in previous devices.

⁵ The descriptive characteristics such as the dimension of the airway opening channel of the device was not clear. In addition, the material composition of the device was not clearly specified.

Contact History

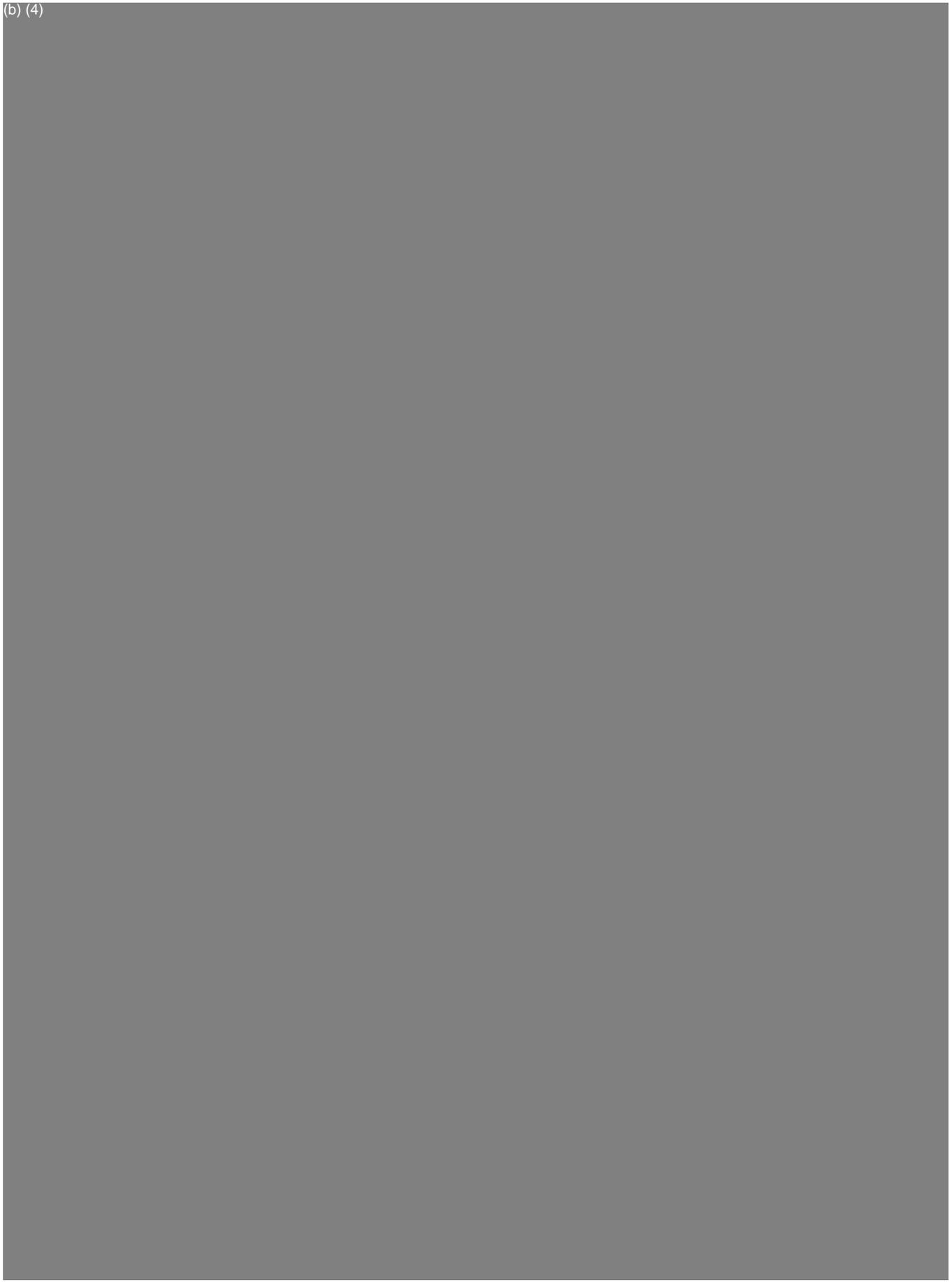
(b) (4)



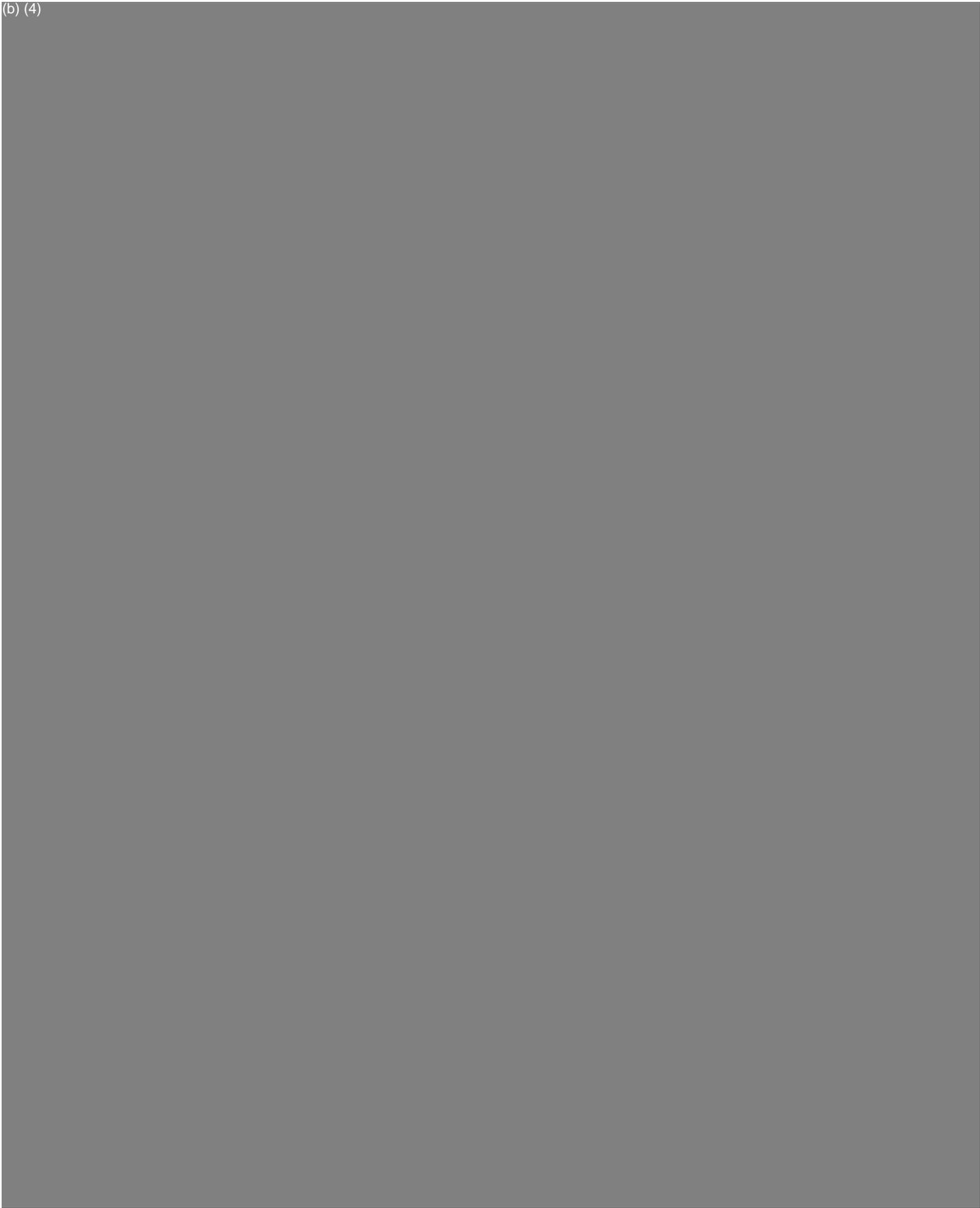
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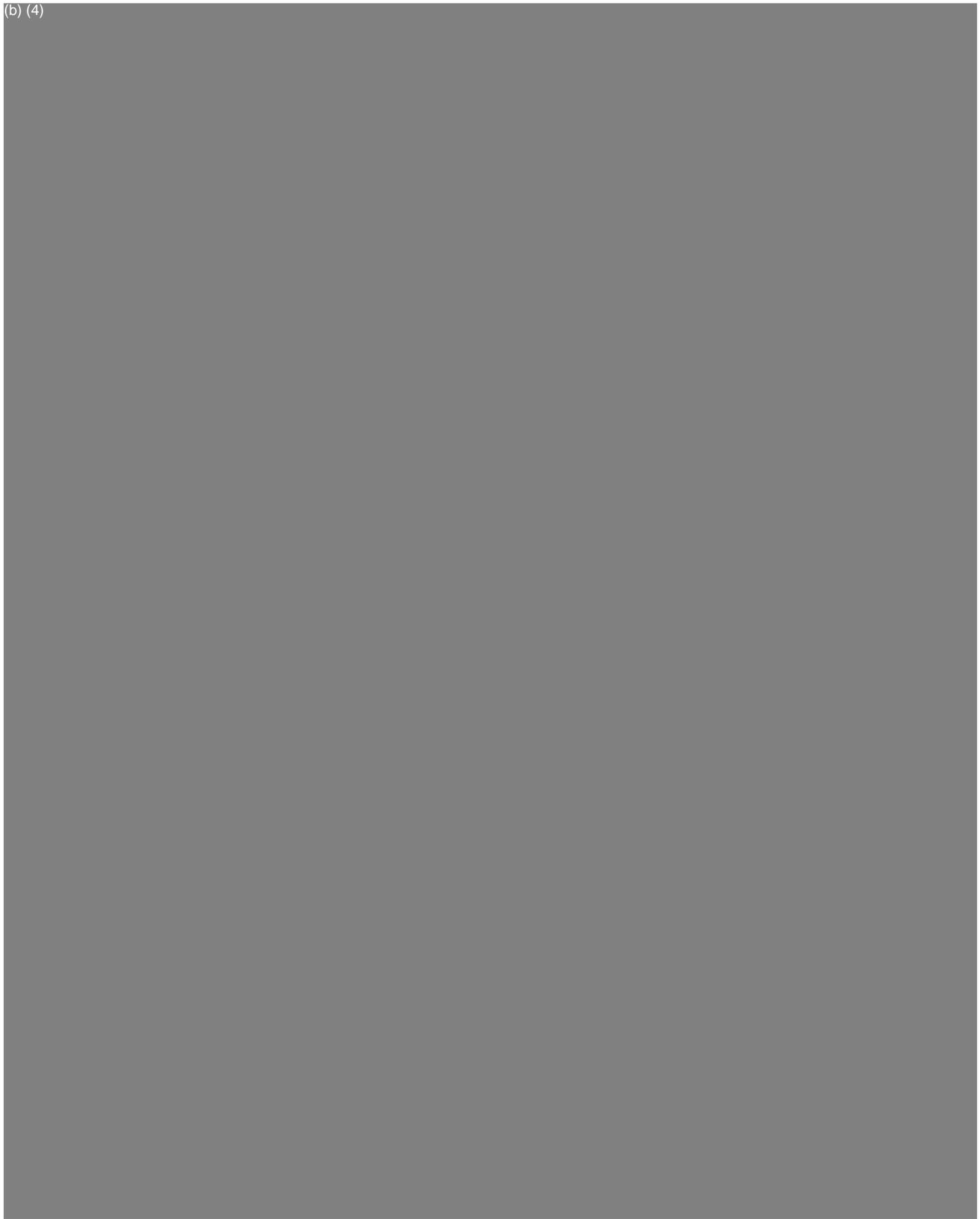
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(b) (4)



(b) (4)



(b) (4)



Recommendation

After review of K112205, K112205/S1, K112205/S2 I recommend that the *SnoreRX NS 9.0* be cleared for marketing.



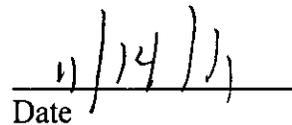
Reviewer
Sheena A. Green
Biomedical Engineer



Date



Branch Chief
M. Susan Runner, DDS., M.A.
Branch Chief Dental Devices



Date

19

Green, Sheena

From: gmocnik@cox.net
Sent: Tuesday, November 01, 2011 6:03 PM
To: Green, Sheena
Subject: Re: K112205/S1: SnoreRX NS - November 1, 2011

Sheena,
Thanks for the response. I will coordinate with my client and get a response back to you shortly

Gary

----- "Green wrote:

> Dear Gary,

(b) (4)



(b) (4)



>
> Best Regards,
>
> Sheena
>
> *****
> Sheena A. Green, M.S.
> Biomedical Engineer/Scientific Reviewer
> U.S. Food & Drug Administration
> ODE/CDRH/DAGID
> Dental Devices Branch
> 10903 New Hampshire Avenue
> WO66 - 2545
> Silver Spring, MD 20993
> Ph: (301) 796-6279
> Fax: (301) 847-8109
> sheena.green@fda.hhs.gov
>
>

> THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY
> CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER
> LAW. If you are not the addressee, or a person authorized to deliver the document to the
> addressee, you are hereby notified that any review disclosure, dissemination, copying, or
> other action based on the content of this communication is not authorized. If you have
> received this document in error, please immediately notify the sender by email or
> telephone. This communication is consistent with 21 CFR 10.85(k) and constitutes an
> informal communication that represents my best judgment at this time but does not
> constitute an advisory opinion, does not necessarily represent the formal position of FDA,
> and does not bind or otherwise obligate or commit the agency to the views expressed.
>
>

Green, Sheena

From: gmocnik@cox.net
Sent: Sunday, October 30, 2011 8:03 PM
To: Green, Sheena
Subject: K112205-response to AI email

Sheena

Just a quick email to see if there is an update on reviewing the information sent to you two weeks ago regarding the above reference submission.
Thanks in advance.

Gary

Green, Sheena

From: gmocnik@cox.net
ent: Tuesday, October 04, 2011 4:26 PM
o: Green, Sheena
Subject: Re: K112205: SnoreRX NS 9.0 - October 3, 2011

Sheena

I have received your email and have forwarded it to the company. I expect that we will respond within two weeks

Thanks in advance

Gary

----- "Green wrote:

> Dear Mr. Mocnik,

(b) (4)



(b) (4)



>
> Best Regards,
>
> Sheena
>
> *****
> Sheena A. Green, M.S.
> Biomedical Engineer/Scientific Reviewer
> U.S. Food & Drug Administration
> ODE/CDRH/DAGID
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> informal communication that represents my best judgment at this time but does not
> constitute an advisory opinion, does not necessarily represent the formal position of FDA,
> and does not bind or otherwise obligate or commit the agency to the views expressed.
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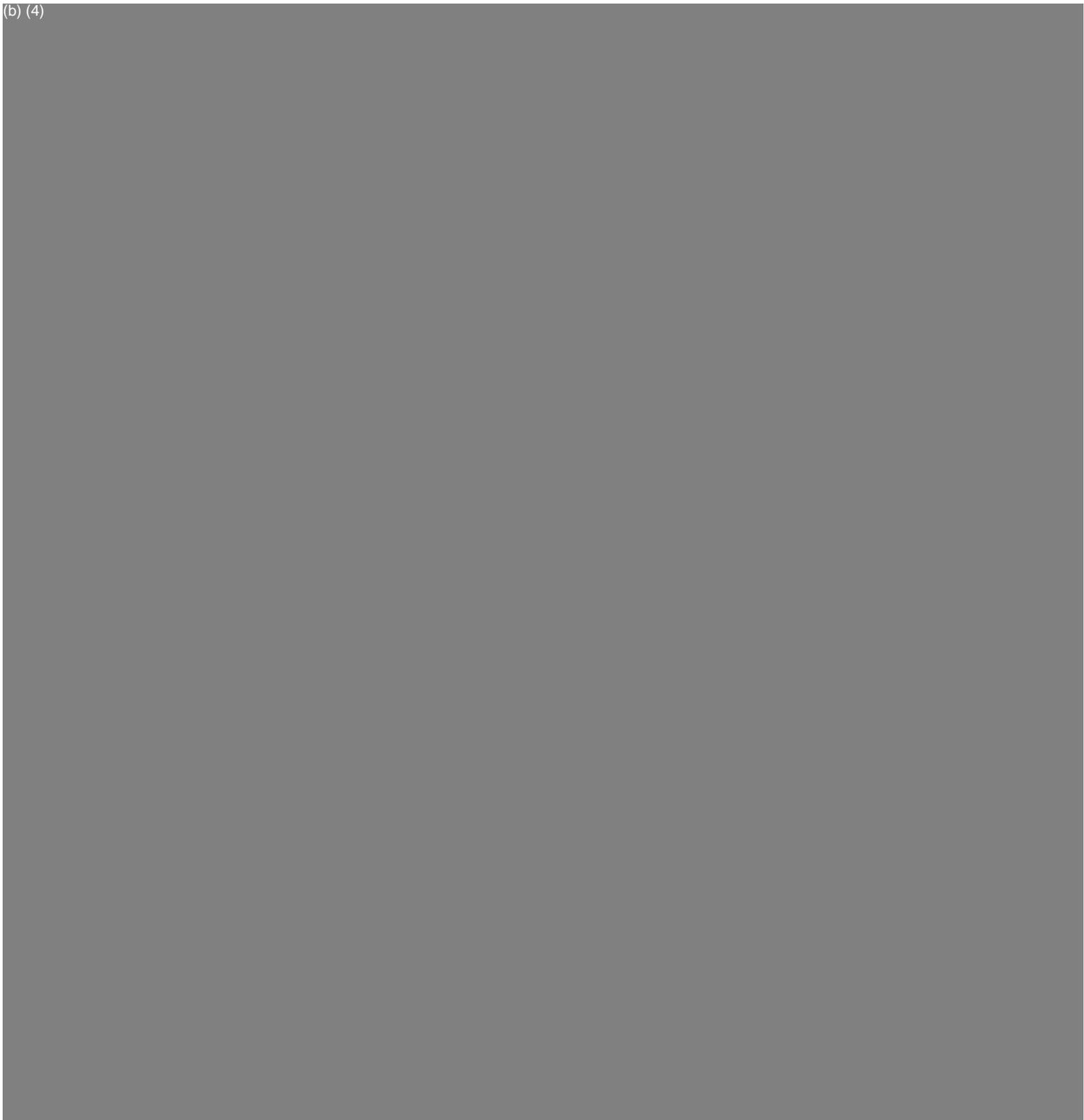
24

Green, Sheena

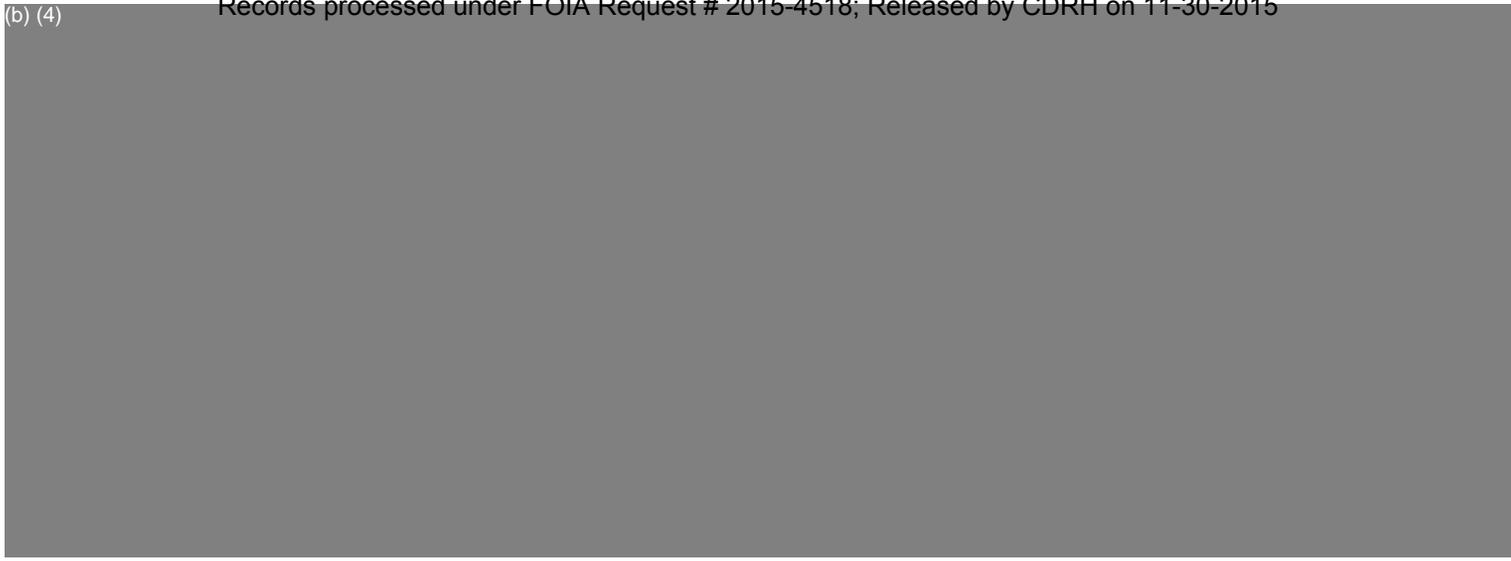
From: Green, Sheena
ent: Tuesday, November 01, 2011 11:23 AM
o: 'gmocnik@cox.net'
Subject: K112205/S1: SnoreRX NS - November 1, 2011

Dear Gary,

(b) (4)



(b) (4)



Best Regards,

Sheena

Sheena A. Green, M.S.

Biomedical Engineer/Scientific Reviewer
U.S. Food & Drug Administration
ODE/CDRH/DAGID
Dental Devices Branch
10903 New Hampshire Avenue
WO66 - 2545
Silver Spring, MD 20993
Ph: (301) 796-6279
Fax: (301) 847-8109
sheena.green@fda.hhs.gov

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Green, Sheena

From: Green, Sheena
ent: Monday, October 31, 2011 10:10 AM
,o: 'gmocnik@cox.net'
Subject: RE: K112205-response to AI email - October 31, 2011

Gary,

Your file is still under review. If and when I have any additional questions you will be notified. Thanks!

Sheena

-----Original Message-----

From: gmocnik@cox.net [mailto:gmocnik@cox.net]
Sent: Sunday, October 30, 2011 8:03 PM
To: Green, Sheena
Subject: K112205-response to AI email

Sheena

Just a quick email to see if there is an update on reviewing the information sent to you two weeks ago regarding the above reference submission.
Thanks in advance.

Gary

Green, Sheena

From: Green, Sheena
Sent: Tuesday, September 20, 2011 5:14 PM
To: 'gmocnik@cox.net'
Subject: RE: K112205

Mr. Mocnik,

Thank you for your e-mail. Your file is currently under review. I cannot estimate if and when I will have questions. Each reviewer has 90 days to render a recommendation on a 510(k) review. If and when I have additional questions you will be contacted.

Best Regards,

Sheena

-----Original Message-----

From: gmocnik@cox.net [mailto:gmocnik@cox.net]
Sent: Tuesday, September 20, 2011 2:59 PM
To: Green, Sheena
Subject: Re: K112205

Ms. Greene

I was forwarded your information from Myra Browne who indicated you are the reviewer for the above reference pre-market notification for the SnoreRx device. I am the Official correspondent for Consumer Health Products. We were interested in understanding the status of the review and if there are any questions.

Any insight into the status and the estimated date for questions or clearance would be appreciated.

Thanks in advance.

Gary Mocnik
Consultant
949.433.0413

Grayson, Giovanna *

From: Microsoft Exchange
To: 'gmocnik@cox.net'
Sent: Monday, November 07, 2011 2:10 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'gmocnik@cox.net'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Monday, November 07, 2011 2:10 PM
To: 'gmocnik@cox.net'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES**Public Health Service**

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center, WO66-G609

10903 New Hampshire Avenue
 Silver Spring, MD 20910-1002

November 07, 2011

MOCNIK

GARY

CONSUMER HEALTH PRODUCTS, INC
 C/O GARY MOCNIK AND ASSOCIATES
 49 COASTAL OAK
 ALISO VIEJO, CALIFORNIA 92656
 ATTN: GARY MOCNIK

510k Number: K112205

Product: SNORERX 9.0

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,
510(k) Staff



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Sheena A. Green
Subject: 510(k) Number K112205/51
To: The Record

Please list CTS decision code TH
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 Hold (Additional Information or Telephone Hold).
 Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

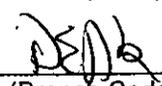
Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf).			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Questions Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118			

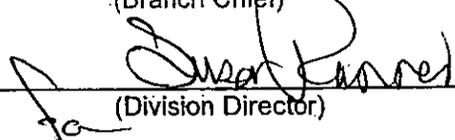
Neonate/Newborn (Birth to 28 days)		
Infant (29 days -< 2 years old)		
Child (2 years -< 12 years old)		
Adolescent (12 years -< 18 years old)		
Transitional Adolescent A (18 - <21 years old). Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		
Nanotechnology		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	

Regulation Number Class* Product Code

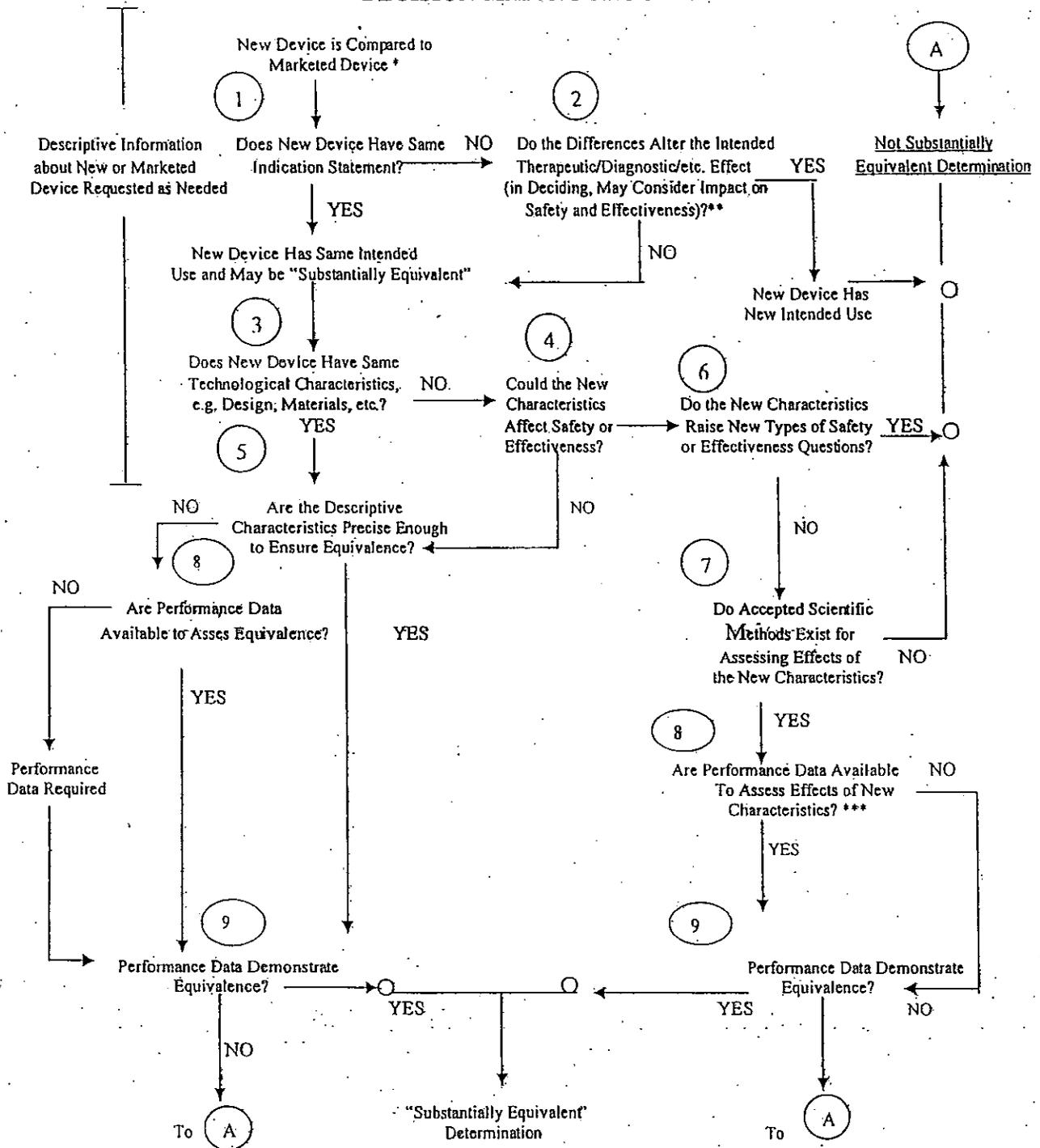
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:   11/1/11
 (Branch Chief) (Branch Code) (Date)

Final Review:  11/1/11
 (Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Questions? Contact FDA/CDRH/OCE/DID at CDRH.FOISTATUS@fda.hhs.gov or 301-796-8118
Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

510(k) Memorandum

TO: The Record

FROM: Sheena A. Green
ODE/DAGID/DEDB

DATE: November 1, 2011

SUBJECT: *SnoreRX NS 9.0 (K112205/A2)*

CONTACT: Gary Mocnik
Regulatory Consultant
Aliso Viejo, CA 92656
Phone: (949)433-0413
Fax: (949)831-9944
Email: gmocnik@cox.net

RECOMMENDATION: Telephone Hold (TH)

Purpose and Submission Summary:

Gary Mocnik & Associates of Aliso Viejo, CA has submitted a pre-market notification (510(k)) on behalf of Consumer Health Products, Inc of Laguna Niguel, CA to introduce the *SnoreRX NS 9.0* into interstate commerce. *SnoreRX NS 9.0* would be regulated as a prescription Class II medical device, and would be classified under 21 CFR 872.5570, as an Intraoral device for snoring and an intraoral device for snoring and obstructive sleep apnea, product code LRK.

The sponsor claims substantial equivalence to the following predicates:

- Snore Guard(K050592)
- Silencer (K954530)
- Snore Control (K963591)
- Pure Sleep (K954128)

The submission claims conformity to the following standard and/or guidance document:

- ISO 10993-1:2003 Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing
- ISO 10993-5:2003 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity
- ISO 10993-10:2003 Biological Evaluation of Medical Devices – Part 10 Intracutaneous

- Irritation Testing
- ISO 10993-11:2003 Biological Evaluation of Medical Devices – Part 11 Sensitization testing
 - Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA, November 12, 2002.
 - FDA Blue Book memorandum G-95

Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

510(k) Summary / 510(k) Statement:

The sponsor has provided a 510(k) summary in the original submission.

		YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)				
	Clearly labeled "510(k) Summary"	X		
	Submitter's name, address, phone #, a contact person	X		
	Date the summary was prepared	X		
	The name of the device/trade name/common name/classification name	X		
	An identification of the legally marketed Predicate	X		
	Description of the subject device	X		
	Statement of intended use(identical to indications for use)	X		
Technological characteristics	if same, a summary of comparison of technological characters	X		
	If different, a summary of how do they compare to the Predicate	X		
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	X		
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> Description upon whom the device was tested, Data obtained from the tests and especially: Adverse events and complications Other information for SE determination 			X
	Conclusion that data demonstrate SE	X		

	YES	NO	N/A
Required Elements for 510(k) Statement (21 CFR 807.93)			
Signed verbatim statement			X

Indications for Use:

The sponsor has provided Indications for Use statement that states: “The Consumer Health Products “SnoreRX NS 9.0” is intended for use on adult patients 18 years or older as an aid for the reduction and /or alleviation of snoring.”

Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are “cleaning” instructions included for the end user?			

SnoreRX NS 9.0 is an intraoral device that is used at night to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface causes *the SnoreRX NS 9.0* to function as a mandibular anterior repositioner. The device employs a “boil & bite” design to provide custom impression for each patient. *The SnoreRX NS 9.0* is boiled for 1 minute, removed and then cooled for 7-10 seconds. It is then placed in the patient’s mouth where they will bite down full force for 30 seconds. The device is then removed and place in a bowl of ice water for 30 seconds which locks in the teeth impression.

The submission states that *SnoreRX NS 9.0* works by allowing the user to adjust the upper or lower trays in 1 mm increments. It locks in the desired setting but also allows for future changes. The device has a “PUSH” button feature that unlocks the setting. By continuing to depress the “PUSH” button, the user is able to move the lower tray into the new desired position and by releasing the “PUSH” button, the new setting is locked in place.

(b)(4)



Predicate Device Comparison

The sponsor claims substantial equivalence to the following predicates: Snore Guard (K050592), Silencer (K954530), and Snore Control (K963591)

The 510(k) number above referenced for the Snore Guard does not match up to what is listed in IMAGE. Therefore, it was requested in the first AI letter that the sponsor to clarify the correct 510(k) number for the Snore Guard device. In S001, the sponsor identified the correct 510(k) number for the Snore Guard as K103004. In addition, in S001 the sponsor identified the Snore Master renamed Pure Sleep (K954128) as an additional predicate.

The subject device was compared to the other two predicates K954530 and K963591. The intended uses of the subject device and predicate devices are similar in that they are all to reduce snoring and are for patients 18 years or older.

The designs of the subject and predicate devices are similar. All devices consist of two parts: upper and lower trays made of a hard acrylic. The trays of the subject device are made from ELVAX 3615 while the trays of the Silencer are made from ELVAX 40. All devices allow mandibular advancement of the patient's jaw. There are differences in the type of mechanism that engages the two trays. The subject device is engaged by a "PUSH" button while the Silencer is engaged by a Halstrom Hinge and clasps. In addition, the labeling of these devices is similar in that they all include similar contra-indications, warnings, and precautions.

Labeling

Proposed labelling for the *SnoreRX NS 9.0* was provided in section 14 of the original submission. The proposed labeling includes a representation of the device label and a draft of the instructions for use manual. The draft of the device label include the device name, the required prescription statement, and a claim that states that the "SnoreRX NS 9.0 is endorsed as a proven clinical treatment for snoring." To support the claim above, the sponsor was asked to provide a few clinical cases. In response in S001, the sponsor removed the claim from the label. Response is acceptable. In addition, the label in the original submission was incomplete. It does not include the company's info such as name, address, etc. Therefore, in the first AI letter the sponsor was asked to revise their label accordingly. A revised label was provided in supplement one that is complete and acceptable.

The draft of the instructions for use manual includes the following: device name, prescription statement, device description, contra-indications, warnings, precautions, info on to prepare for fitting of the device, fitting protocol, cautions, and info on care of device.

It appears from the instructions for use in the original submission that both the patient and dentist fit this device. Typically, these types of devices are fitted by the dentist in his or her office; therefore it was recommended that the sponsor remove instructions that instruct the patient to fit the device and provide specific instructions for the dentist on how to prepare and fit the device. In addition, it was recommended that the sponsor provide separate patient instructions on how to care and store their device. The sponsor responded in S001 identifying a predicate device that was cleared in '95 that included instructions where it seems like the patient was involved in the fitting of the device. However, base on the Agency's knowledge about these type of these devices and current standard practices it is recommended that each sponsor provide

both separate instructions for the dentist on how to fit the device etc and for the patient on how to care and store their device as recommended by the guidance document *Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA* issued November 12, 2002. Therefore, the identification of the additional predicate in S001 by the sponsor is not adequate in addressing this labeling issue; therefore the sponsor will be asked again in the second AI letter to provide clear and concise dentist instructions and patient instructions as recommended by the guidance document above.

In the original submission specifically the instructions for use, device description and executive summary the sponsor claims that their device "eliminates snoring." It was recommended that the sponsor provide the appropriate data to support such claim or alternatively remove it. In S001, the sponsor removed the claim that their device "eliminates snoring" from the device description and executive summary; however the claim was removed from the instructions for use. Again, the sponsor will be asked in the second AI letter to provide the appropriate data for the claim or alternatively remove it from the revised instructions for use as well. In addition, the revised instructions for use do not include the indications for use statement. The sponsor will be asked to revise the instructions for use to include identical indications as the one written on the IFU form.

Sterilization/Shelf life/Reuse

The *SnoreRX NS 9.0* is provided non-sterile as are other similar cleared devices. These devices are provided non-sterile and are not intended to be sterilized. In addition, similarly to other intraoral snoring and/or OSA devices, *SnoreRX NS 9.0* is for single patient – multi use.

Biocompatibility

The sponsor identified two materials that are used to fabricate the major components of the *SnoreRX NS 9.0*. These materials are [REDACTED] (b)(4) [REDACTED]. [REDACTED] [REDACTED]. Section 16 of the original submission states that two above materials have been tested in according to the guidances given in ISO 10993-1, 5, 10 as well as FDA Blue Book memorandum G-95. Table 16-2 in section 16 summarized the test results if the Easter Copolyester material. The results in the table suggest that this material is non-cytotoxic, non-irritant, and negative for evidence of sensitization. For the ELVAX 3165, the sponsor notes that they did not conduct biocompatibility testing on this material but testing was conducted by the supplier Dupont. A letter was referenced in which the sponsor notes is available from the [REDACTED] (b) [REDACTED] is biocompatible.

The biocompatibility information above provided by the sponsor in the original submission is unacceptable, because it does not appear that testing was conducted on the final device but rather the two above materials alone. In addition, providing a summary of the test results is not sufficient, it is recommended that the sponsor provide the actual full test reports for review. Finally, obtaining a letter from the supplier that states that a material is biocompatible is not adequate. Again, this letter must be supported by the actual test reports. In conclusion, the sponsor was asked in the first AI letter to clarify whether biocompatibility testing was performed on the final device and if so full test reports must be provided for review. Alternatively, the sponsor may identify a predicate that uses the same materials (with exact chemical compositions) with the same intended uses as the ones identified in this device.

In response, the sponsor identified predicate devices that utilize the same material composition of the materials used in the subject device. Such predicate devices include Snore Master now known as Pure Sleep (K954128). In addition, to support the biocompatibility claim the sponsor provided comparative testing to confirm the based on analytical chemistry evaluations (Infrared Spectroscopy abs Differential Scanning Calorimetry) the materials of the subject device and the listed predicate device share equivalent chemical compositions. The colorants identified in the subject device are [REDACTED] [REDACTED] (b)(4) To support the use of the colorants above the sponsor provided a supporting document (letter) from the supplier that states that these colorants are safe for use; however this does not adequately address the concern that with the addition of the colorants there maybe a change in the biocompatibility properties of the device. Also, the analytical chemistry evaluation testing provided appears to be incomplete and difficult to read. Therefore the sponsor will be asked in the second AI letter to provide clear and complete of the analytical chemistry tested performed on their device or alternatively provide a signed biocompatibility certification that states that "*The combination of raw materials that make up the final product {device name} is identical to the finished products {predicates}. Therefore it can be concluded that the {device name} share the same biocompatibility with {predicate devices}.*"

Software

This device does not utilize software; therefore this section is not applicable.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

No electrical components are contained in the *SnoreRX NS 9.0*.

Performance Testing – Bench

The sponsor notes in section 19 that bench testing was conducted on the *SnoreRX NS 9.0* and samples of the device were tested to establish performance of key design features to substantiate equivalence. It is stated that all samples tested were representatives of finished devices. The tests conducted included an approved Risk Analysis, visual inspection, engineering and failure analysis, and a dimensional analysis.

The objective of the visual inspection was to verify that the device was free from any sharp edges that would result in harm of the patient. The purpose of the engineering and failure analysis was to verify that the device integrity was maintained throughout the evaluation. The dimensions of the airway channels of the device were studied during the dimensional analysis. This test was to assure that there is adequate airflow to accommodate full mouth breathing during sleep.

In the original submission summaries of the above tests were provided rather than the actual test reports. In addition, it was not clear on how the acceptance criteria for these tests were defined. It was recommended in the first AI letter that the sponsor provide full test reports for the bench tests above performed on their device and to clarify how the acceptance criteria for each test were established. In response, in S001 full test reports were provided and the acceptance criteria were defined by the predicate devices' specifications. The results of the Risk Analysis, visual inspection, and a dimensional analysis tests do not support the performance of this device but

rather the appearance of the device. To address the concern that there maybe insufficient space for air to flow through the patient's mouth to accomodate full mouth breathing during sleep the sponsor provided dimensional cross sections between the subject device and Pure Sleep (K954128). It is not clear from the information how some of the referenced measurements were obtained. The sponsor will be asked in the second AI letter to provide a thorough test report or alternatively provide some clinical cases that demonstrate successful use of this device.

Performance Testing – Animal

No animal test results are required to determine substantial equivalence of these types of devices.

Performance Testing – Clinical

No clinical data was provided in the original submission; however the sponsor stated on the draft of their device label in the original submission that "SnoreRX NS 9.0 is endorsed as a proven clinical treatment for snoring." Sponsor was asked to justify such claim with the appropriate data or alternatively remove it. In response, the sponsor revised their device label to remove the above claim.

Substantial Equivalence Discussion

	YES	NO
1. Same Indication Statement?		X If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		X If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: TH

Contact History

(b) (4)



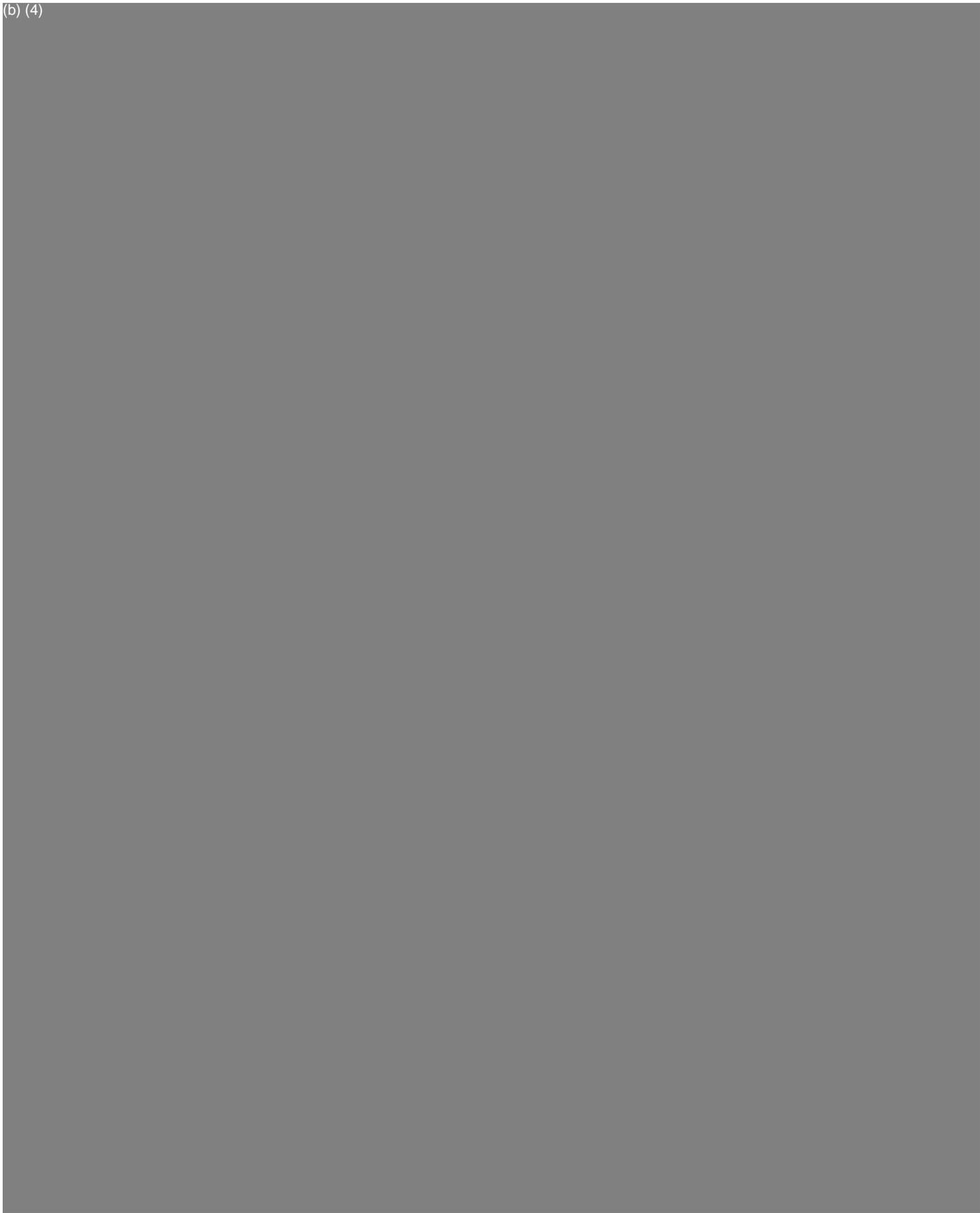
(b) (4)



(b) (4)

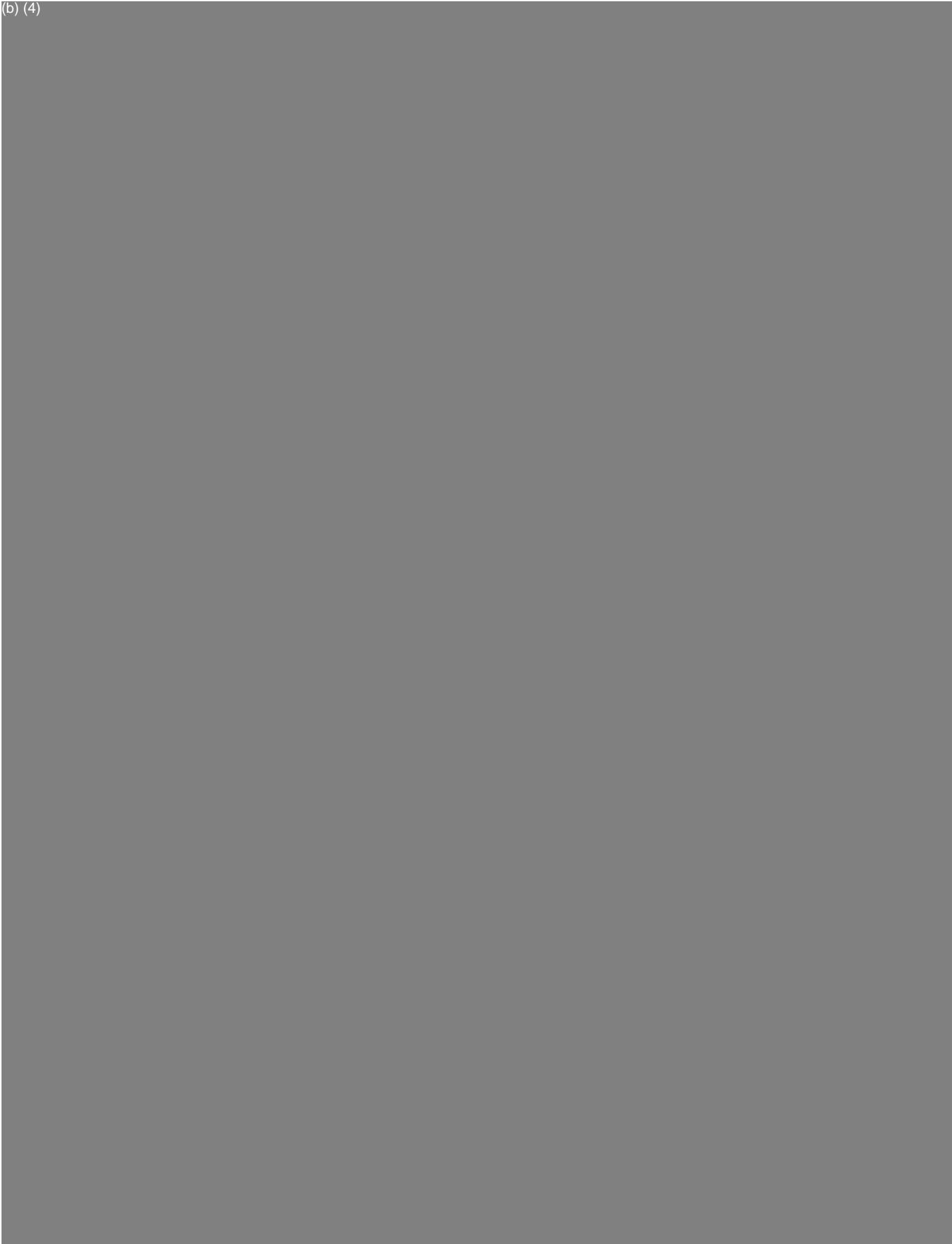


(b) (4)



72

(b) (4)

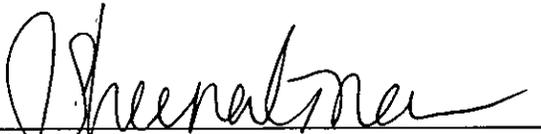


(b) (4)

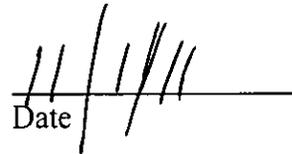


Recommendation

After review of K112205 and K112205/S1 I recommend that this file be placed back on **telephone hold** until all of the deficiencies above dated November 1, 2011 are adequately addressed.



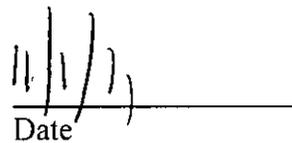
Reviewer
Sheena A. Green
Biomedical Engineer



Date



Branch Chief
M. Susan Runner, DDS., M.A.
Branch Chief Dental Devices



Date

Green, Sheena

From: Green, Sheena
Sent: Tuesday, November 01, 2011 11:23 AM
To: 'gmocnik@cox.net'
Subject: K112205/S1: SnoreRX NS - November 1, 2011

Dear Gary,

(b) (4)



Best Regards,

Sheena

Sheena A. Green, M.S.

Biomedical Engineer/Scientific Reviewer
U.S. Food & Drug Administration
ODE/CDRH/DAGID
Dental Devices Branch
10903 New Hampshire Avenue
WO66 - 2545
Silver Spring, MD 20993
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sheena.green@fda.hhs.gov

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COVER SHEET MEMORANDUM

From: Reviewer Name Sheena A. Green
 Subject: 510(k) Number K112205
 To: The Record

Please list CTS decision code TH

Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

Hold (Additional Information on Telephone Hold)

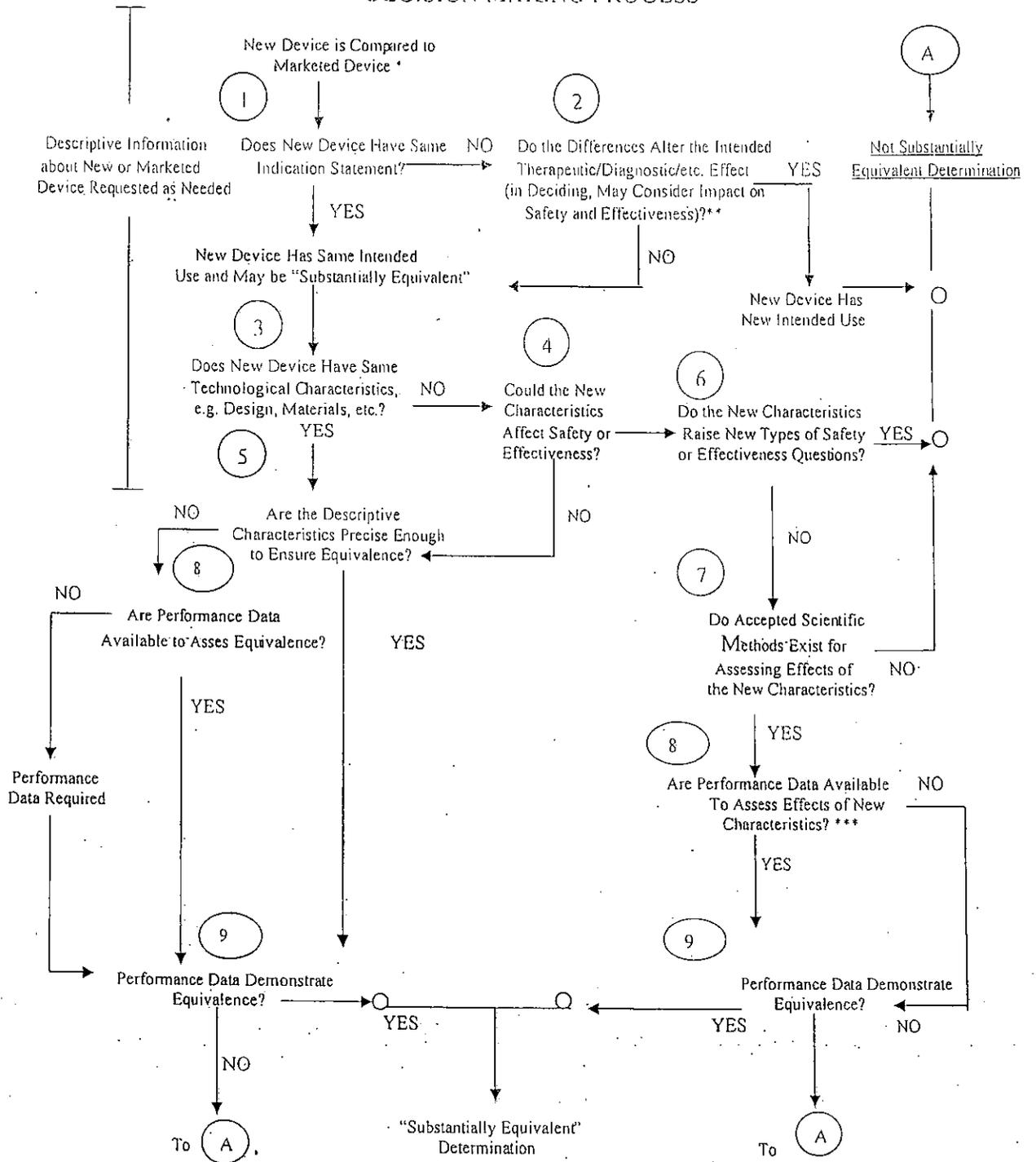
Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>		
510(k) Summary /510(k) Statement	<i>Attach Summary</i>		
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>		
Is the device Class III?			
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf).			
Is this a combination product? (Please specify category _____, see http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

510(k) Memorandum

TO: The Record

FROM: Sheena A. Green
ODE/DAGID/DEDB

DATE: October 3, 2011

SUBJECT: *SnoreRX NS 9.0 (K112205/A1)*

CONTACT: Gary Mocnik
Regulatory Consultant
Aliso Viejo, CA 92656
Phone: (949)433-0413
Fax: (949)831-9944
Email: gmocnik@cox.net

RECOMMENDATION: Telephone Hold (TH)

Purpose and Submission Summary

Gary Mocnik & Associates of Aliso Viejo, CA has submitted a pre-market notification (510(k)) on behalf of Consumer Health Products, Inc of Laguna Niguel, CA to introduce the *SnoreRX NS 9.0* into interstate commerce. *SnoreRX NS 9.0* would be regulated as a prescription Class II medical device, and would be classified under 21 CFR 872.5570, as an Intraoral device for snoring and an intraoral device for snoring and obstructive sleep apnea, product code LRK.

The sponsor claims substantial equivalence to the following predicates:

- Snore Guard(K050592)
- Silencer (K954530)
- Snore Control (K963591)

The submission claims conformity to the following standard and/or guidance document:

- ISO 10993-1:2003 Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing
- Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA, November 12, 2002.
- FDA Blue Book memorandum G-95

Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

510(k) Summary / 510(k) Statement

The sponsor has provided a 510(k) summary in the original submission.

		YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)				
	Clearly labeled "510(k) Summary"	X		
	Submitter's name, address, phone #, a contact person	X		
	Date the summary was prepared	X		
	The name of the device/trade name/common name/classification name	X		
	An identification of the legally marketed Predicate	X		
	Description of the subject device	X		
	Statement of intended use (identical to indications for use)	X	X	
Technological characteristics	if same, a summary of comparison of technological characters		X	
	If different, a summary of how do they compare to the Predicate		X	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination 		X	
	Conclusion that data demonstrate SE		X	
Required Elements for 510(k) Statement (21 CFR 807.93)				
	Signed verbatim statement			X

Indications for Use

The sponsor has provided Indications for Use statement that states: "The Consumer Health Products "SnoreRX NS 9.0" is intended for use on adult patients 18 years or older as an aid for the reduction and /or alleviation of snoring."

Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	

	Yes	No	N/A
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?			

SnoreRX NS 9.0 is an intraoral device that is used at night to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface causes the *SnoreRX NS 9.0* to function as a mandibular anterior repositioner. The device employs a "boil & bite" design to provide custom impression for each patient. The *SnoreRX NS 9.0* is boiled for 1 minute, removed and then cooled for 7-10 seconds. It is then placed in the patient's mouth where they will bite down full force for 30 seconds. The device is then removed and placed in a bowl of ice water for 30 seconds which locks in the teeth impression.

The submission states that *SnoreRX NS 9.0* works by allowing the user to adjust the upper or lower trays in 1 mm increments. It locks in the desired setting but also allows for future changes. The device has a "PUSH" button feature that unlocks the setting. By continuing to depress the "PUSH" button, the user is able to move the lower tray into the new desired position and by releasing the "PUSH" button, the new setting is locked in place.

Two main components are used to fabricate the *SnoreRX NS 9.0*. The upper and lower trays are fabricated from (b)(4) and the impression material is (b)(4).

(b)(4) The sponsor notes that the above materials have been used in previously cleared device.

Reviewer's note: The sponsor will be asked to identify each component of the device including the "PUSH" button and their material compositions. In addition, the sponsor will be asked to identify a predicate in which each identified material has been previously cleared along with their CAS numbers where applicable (deficiency #1, A001).

Predicate Device Comparison

The sponsor claims substantial equivalence to the following predicates: Snore Guard (K050592), Silencer (K954530), and Snore Control (K963591)

The 510(k) number above referenced for the Snore Guard does not match up to what is listed in IMAGE.

Reviewer's note: The sponsor will be asked to clarify the correct 510(k) number for the Snore Guard device (deficiency #2, A001).

The subject device was compared to the other two predicates K954530 and K963591. The intended uses of the subject device and predicate devices are similar in that they are all to reduce snoring and are for patients 18 years or older.

The designs of the subject and predicate devices are similar. All devices consist of two parts: upper and lower trays made of a hard acrylic. The trays of the subject device are made from ELVAX 3615 while the trays of the Silencer are made from ELVAX 40. All devices allow mandibular advancement of the patient's jaw. There are differences in the type of mechanism that engages the two trays. The subject device is engaged by a "PUSH" button while the Silencer is engaged by a Halstrom Hinge and clasps. In addition, the labeling of these devices is similar in that they all include similar contra-indications, warnings, and precautions.

Labeling

Proposed labelling for the *SnoreRX NS 9.0* was provided in section 14 of the original submission. The proposed labeling includes a representation of the device label and a draft of the instructions for use manual. The draft of the device label include the device name, the required prescription statement, and a claim that states that the "SnoreRX NS 9.0 is endorsed as a proven clinical treatment for snoring."

Reviewer's note: To support the claim above, the sponsor will be asked to provide a few clinical cases. In addition, the label above is incomplete. It does not include the company's info such as name, address, etc. The sponsor will be asked to revise their label accordingly (deficiency #3, A001).

The draft of the instructions for use manual includes the following: device name, prescription statement, device description, contra-indications, warnings, precautions, info on to prepare for fitting of the device, fitting protocol, cautions, and info on care of device.

Reviewer's note: It appears from the instructions for use that both the patient and dentist fit this device. Typically, these types of devices are fitted by the dentist in his or her office; therefore it will be recommended that the sponsor remove instructions that instruct the patient to fit the device and provide specific instructions for the dentist on how to prepare and fit the device. In addition, it will be recommended that the sponsor provide separate patient instructions on how to care and store their device (deficiency #4, A001).

Reviewer's note: In addition in the instructions for use and throughout the labeling specifically device description and executive summary the sponsor claims that their device "eliminates snoring." It will be recommended that the sponsor provide the appropriate data to support such claim or alternatively remove it (deficiency #5, A001).

Sterilization/Shelf life/Reuse

The *SnoreRX NS 9.0* is provided non-sterile as are other similar cleared devices. These devices are provided non-sterile and are not intended to be sterilized. In addition, similarly to other intraoral snoring and/or OSA devices, *SnoreRX NS 9.0* is for single patient – multi use.

Biocompatibility

The sponsor identified two materials that are used to fabricate the major components of the *SnoreRX NS 9.0*. These materials are (b)(4). Specifically, it is noted that the upper and lower trays of the device are made from (b)(4) (b)(4); and the impression material is (b)(4). Section 16 of the original

submission states that two above materials have been tested in accordance with the guidances given in ISO 10993-1, 5, 10 as well as FDA Blue Book memorandum G-95. Table 16-2 in section 16 summarized the test results for the (b)(4). The results in the table suggest that this material is non-cytotoxic, non-irritant, and negative for evidence of sensitization. For the (b)(4), the sponsor notes that they did not conduct biocompatibility testing on this material but testing was conducted by the supplier Dupont. A letter was referenced in which the sponsor notes is available from the Dupont that states (b)(4) is biocompatible.

(b)(4)

Software

This device does not utilize software; therefore this section is not applicable.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

No electrical components are contained in the *SnoreRX NS 9.0*.

Performance Testing – Bench

The sponsor notes in section 19 that bench testing was conducted on the *SnoreRX NS 9.0* and samples of the device were tested to establish performance of key design features to substantiate equivalence. It is stated that all samples tested were representatives of finished devices. The tests conducted included an approved Risk Analysis, visual inspection, engineering and failure analysis, and a dimensional analysis.

The objective of the visual inspection was to verify that the device was free from any sharp edges that would result in harm of the patient. The purpose of the engineering and failure analysis was to verify that the device integrity was maintained throughout the evaluation. The dimensions of the airway channels of the device were studied during the dimensional analysis. This test was to assure that there is adequate airflow to accommodate full mouth breathing during sleep.

Reviewer's note: Summaries of the above tests were provided rather than the actual test reports. In addition, it is not clear on how the acceptance criteria for these tests were defined. It will be recommended that the sponsor provide full test reports for the bench tests above performed on their device and to clarify how the acceptance criteria for each test were established (deficiency #7, A001).

Performance Testing – Animal

No animal test results are required to determine substantial equivalence of these types of devices.

Performance Testing – Clinical

No clinical data was provided in the original submission; however the sponsor states on the draft of their device label that “SnoreRX NS 9.0 is endorsed as a proven clinical treatment for snoring.” (See labeling above)

Substantial Equivalence Discussion

	YES	NO
1. Same Indication Statement?		X If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		X If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: TH

(b) (4)



(b) (4)



(b) (4)



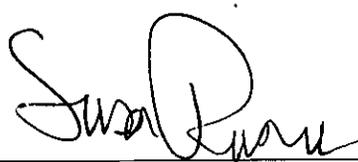
Recommendation

After review of K112205 I recommend that this file be placed on **telephone hold** until all of the deficiencies above are adequately addressed.



Reviewer
Sheena A. Green
Biomedical Engineer

10/3/11
Date



Branch Chief
M. Susan Runner, DDS., M.A.
Branch Chief Dental Devices

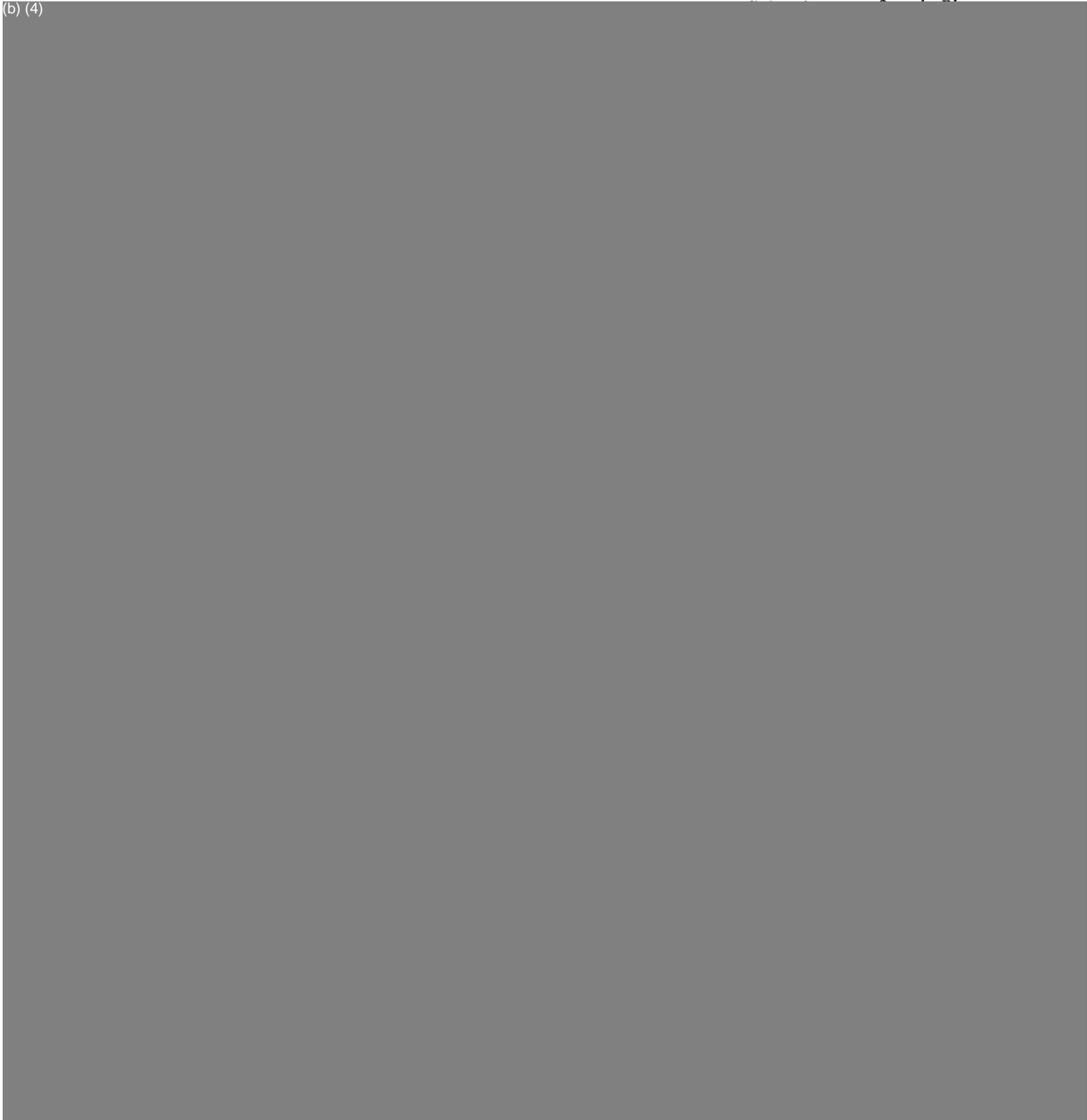
10/3/11
Date

Green, Sheena

From: Green, Sheena
Sent: Monday, October 03, 2011 10:36 AM
To: 'gmocnik@cox.net'
Subject: K112205: SnoreRX NS 9.0 - October 3, 2011

Dear Mr. Mocnik,

(b) (4)





Best Regards,

Sheena

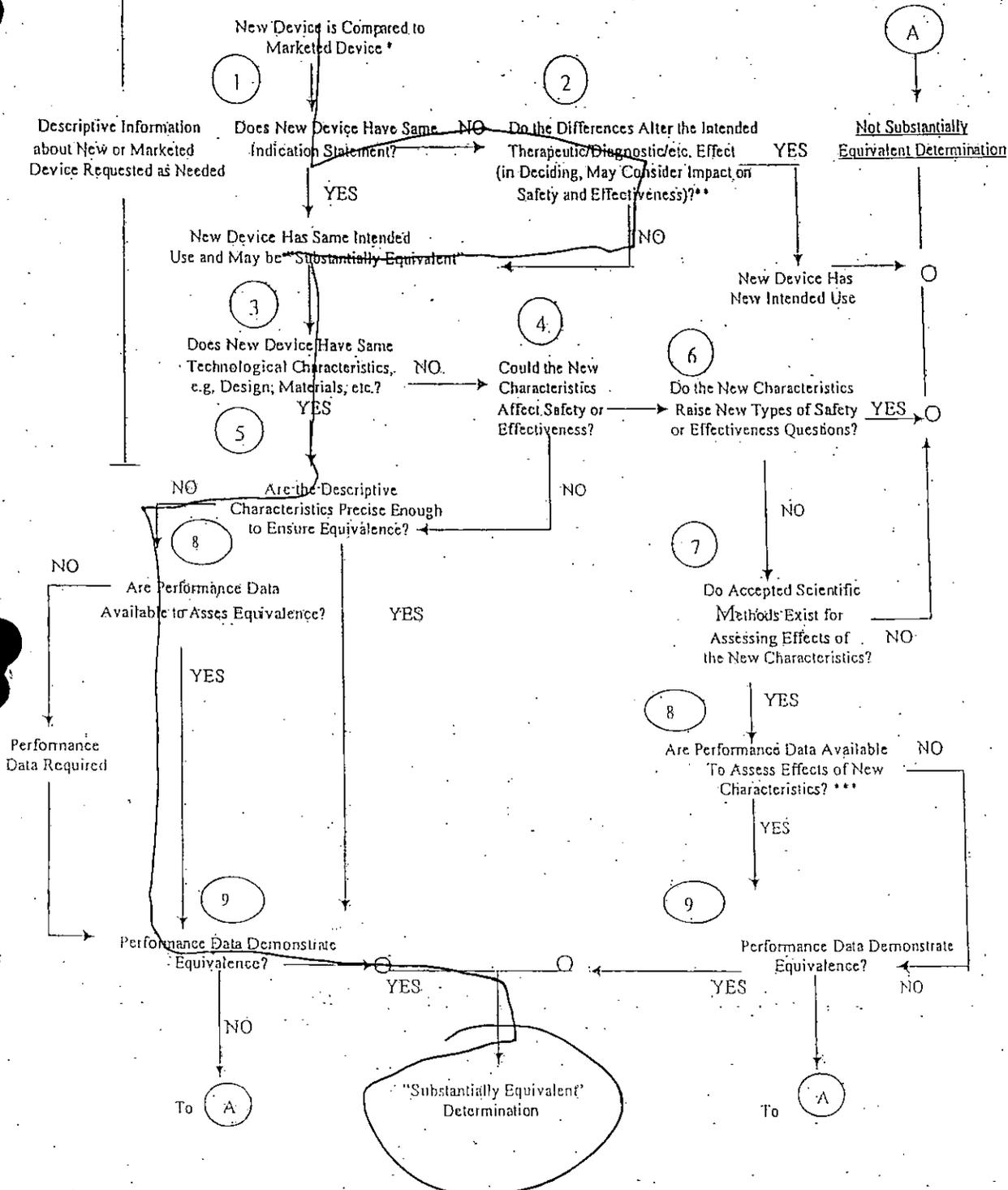
Sheena A. Green, M.S.

Biomedical Engineer/Scientific Reviewer
U.S. Food & Drug Administration
ODE/CDRH/DAGID
Dental Devices Branch
10903 New Hampshire Avenue
WO66 - 2545
Silver Spring, MD 20993
Ph: (301) 796-6279
Fax: (301) 847-8109
sheena.green@fda.hhs.gov

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172

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 18, 2011

CONSUMER HEALTH PRODUCTS, INC
C/O GARY MOCNIK AND ASSOCIATES
49 COASTAL OAK
ALISO VIEJO, CALIFORNIA 92656
ATTN: GARY MOCNIK

510k Number: K112205

Product: SNORERX 9.0

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

77

K112205/51

FDA CDRH DMC

OCT 18 2011

Received

Gary S. Mocnik & Associates
Regulatory Consultants
49 Coastal Oak
Aliso Viejo, California 92656
949-433-0413

October 17, 2011

Ms. Sheena Green
Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: SnoreRx NS 9.0 (K112205)
Email communication dated 10-03-2011

Dear Ms. Green,

Thank you for your efforts in reviewing this premarket notification. The following is in response to your email communication dated October 3, 2011 requesting additional information regarding the above referenced submission. The FDA request is repeated in italics followed by the company's response. Additionally, in responding to several of the agency requests we have identified an additional predicate device, the "PureSleep" (formerly known as "SnoreMaster" and cleared under K954128), that has the same technological features, the same intended use, is constructed from identical materials, and has the same operating principles as the proposed device.

We believe that these responses adequately address the issues raised by the agency and are adequate to determine substantial equivalency to the predicate devices.

Thank you for your consideration of this response. If you have any questions or need any further information, please contact me at (949) 433-0413. Please also note that Jim Fallon (principle of Consumer Health Products) should be considered an authorized respondent for this submission.

Sincerely,



Gary S. Mocnik
Official Correspondent for Consumer Health Products

K-33

(b) (4)



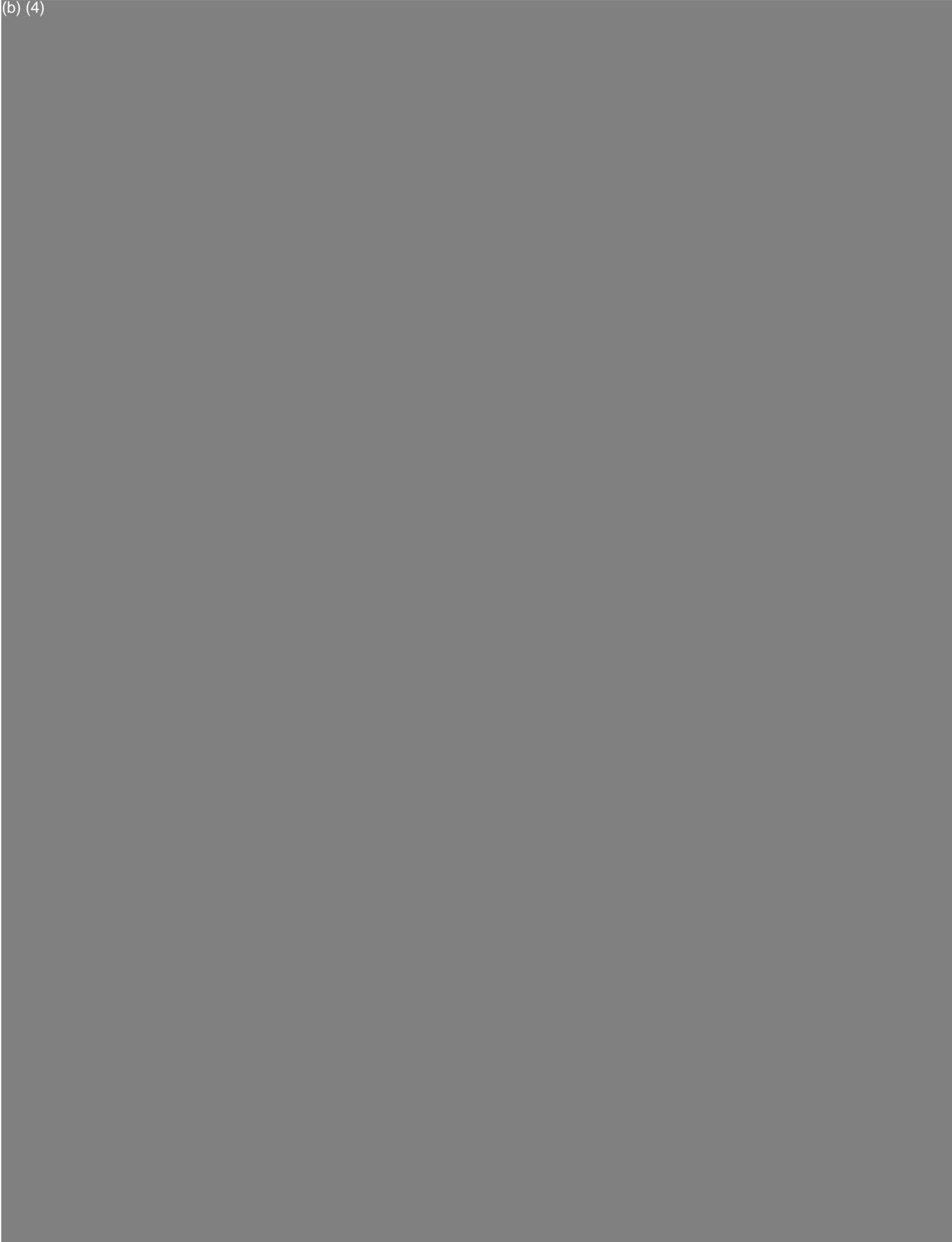
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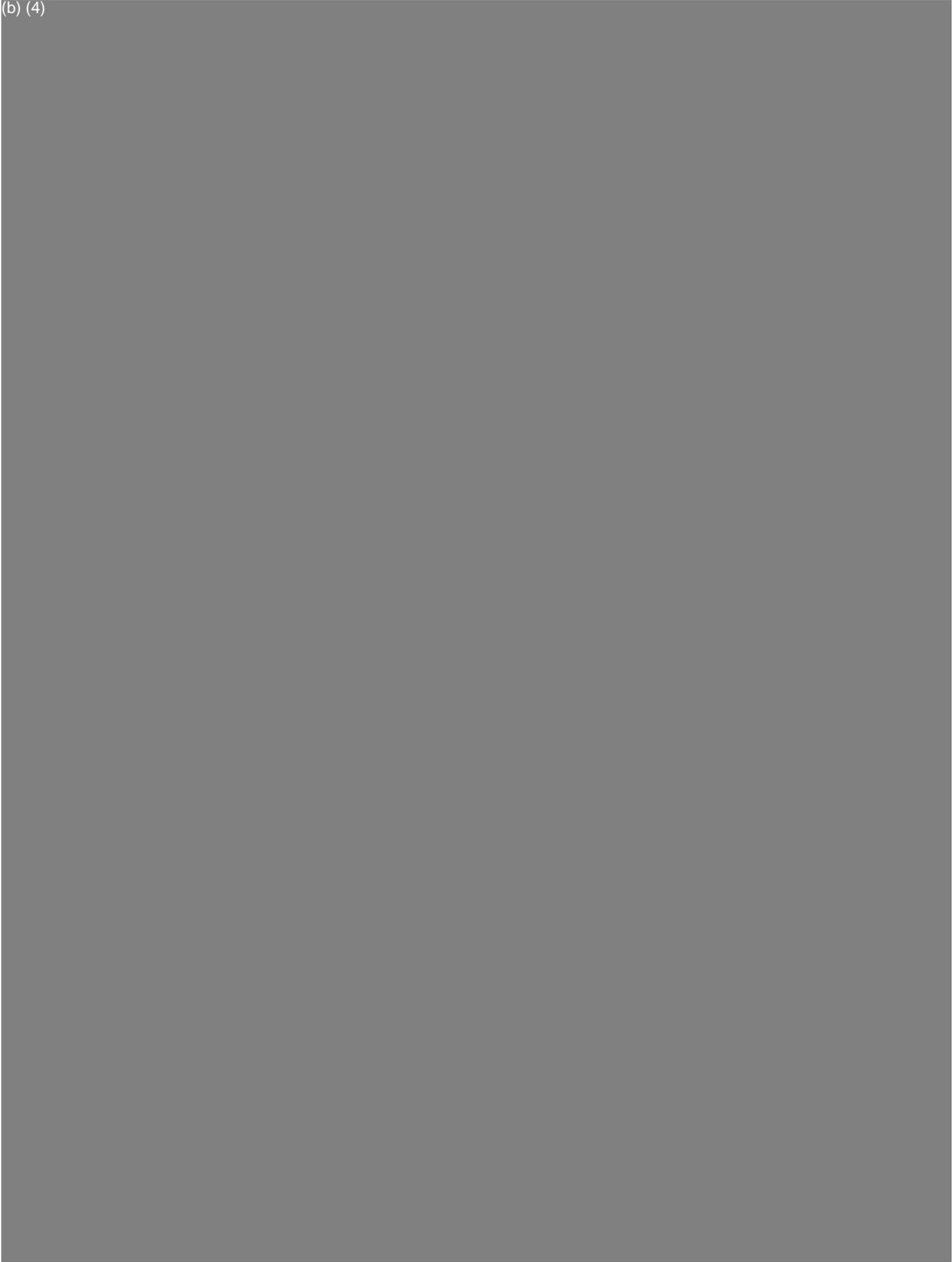
(b) (4)



(b) (4)



(b) (4)



(b) (4)



Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Attachments for Item 2

K103004

FEB 25 2011

510(k) Summary

Ranir's Snore Guard

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Ranir, LLC
4701 East Paris Avenue SE
Grand Rapids, MI 49512
Phone: (616) 698-8880
Facsimile: (616) 656-7650

Contact Person: Jeff Fisher

Date Prepared: December 13, 2010

Name of Device

Snore Guard

Common or Usual Name/Classification Name

Intraoral Anti-Snoring Device

Predicate Devices

Snore Guard Advance (K102118)
SleepRight Original (K100545)

Purpose of Submission

The Snore Guard is a modification to the Snore Guard Advance.

Intended Use / Indications for Use

The Snore Guard is indicated for use in the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in adults 18 years of age or older.

Technological Characteristics

The Snore Guard consists of a mouthguard worn on the maxilla, connected to an occlusal stop (called an "occlusal ramp"), which contacts the patient's mandibular incisors. Both the maxillary tray and the occlusal ramp are custom fitted using a "boil-and-bite" process.

Substantial Equivalence

The Snore Guard has the same intended use and similar indications, principles of operation, and technological characteristics as Snore Guard. The minor differences in the Snore Guard's technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Snore Guard is substantially equivalent to its identified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WD366-G689
Silver Spring, MD 20991-0002

Ranir, LLC
C/O Mr. Gerard J. Prud'homme
Hogan Lovells US LLP
555 Thirtieth Street, NW
Washington, District of Columbia 20004

FEB 25 2011

Re: K103004
Trade/Device Name: Snore Guard
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: LRK
Dated: February 17, 2011
Received: February 17, 2011

Dear Mr. Prud'homme:

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.

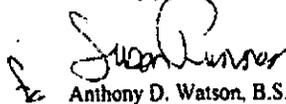
Page 2- Mr. Prud'homme

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" (21 CFR 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,



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

K103004

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Snore Guard

Indications for Use:

The Snore Guard is indicated for use in the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in adults 18 years of age or older.

Prescription Use X
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use _____
(Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: _____

K103004

Attachment for Item 3

DRAFT BOX FRONT LABEL



DRAFT BOX BACK LABEL



Attachment 4.1
PureSleep Instructions For Use

PureSleep
The Stop Snoring Solution

Instruction Guide

*Please read carefully
before using.*



Discover the proven PureSleep[®] Solution—tonight!

www.puresleep.com

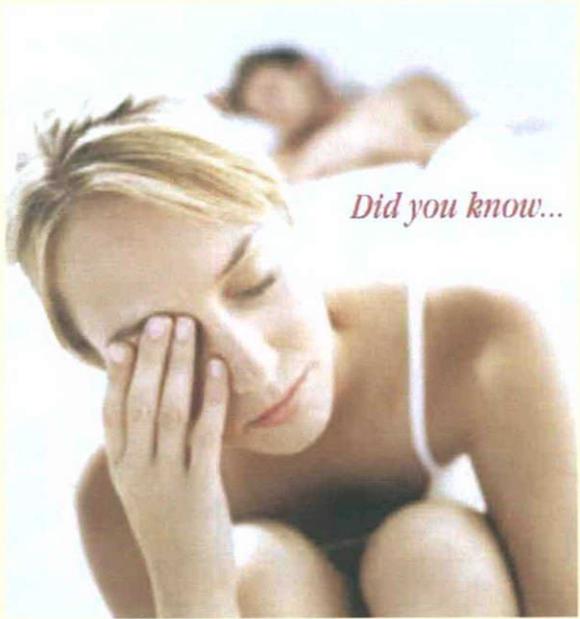
Why You Snore...

Most snoring is caused by a partial obstruction of the upper airway (the region behind the tongue). When we're awake, we consciously keep our upper airway open, allowing unobstructed breathing.

But when people fall asleep, those muscles relax, and the airway can become narrower. For most people who snore, air rushing through the narrowed opening causes the soft tissue in this part of the upper airway to vibrate, making the familiar sound of snoring.



*Proven PureSleep is
as easy to use as a
dental retainer.*



Did you know...

in the U.S. alone, more than 23% of married couples report that they sleep separately because of interrupted sleep, with snoring being the most common problem.

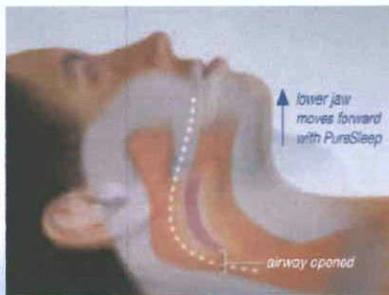
STOP SNORING

Why PureSleep® works.

PureSleep is an intraoral device designed to reduce or eliminate snoring by holding your lower jaw slightly forward of its normal position while you sleep. This tends to widen the upper airway so air isn't forced through such a narrow opening. PureSleep works because it opens your upper airway and eliminates the vibrations we all know as snoring. It's that simple—and that effective!



The soft tissue at the back of the throat relaxes during sleep partially blocking the passageway. Air passing through causes vibration—and the unmistakable sound of snoring.



The principle of PureSleep is simple: it moves your lower jaw forward, opening the passageway enough so that air moves through unobstructed. No vibration, no snoring!

4

www.puresleep.com

Do not use PureSleep if...

- You have been diagnosed with central sleep apnea. PureSleep is not a treatment for sleep apnea or any other medical condition.
- You have chronic asthma, emphysema, or any other severe respiratory disorder. If you have a history of any of these diseases, consult a physician prior to use.
- You have loose teeth, abscesses, or severe gum disease.
- You are less than 18 years of age.
- You have had a dental implant within the last year.
- You have been diagnosed with temporomandibular disorder (TMD), which is a disease of the "jaw joint", unless a dentist or physician has advised you that you may use PureSleep.
- You have full dentures or are undergoing orthodontic treatment.
- The package seal was broken when you received your PureSleep.

If you are unable to use your PureSleep for any of these reasons, please return it for a refund per the terms of the PureSleep 30 day money-back guarantee.

Did you know...

snoring can be a symptom of sleep apnea which is a serious medical condition that can lead to high blood pressure, heart disease and stroke. For more information about sleep apnea, go to sleepapnea.org

GO TO
SLEEP

How to prepare for fitting.

- 1. Brush your teeth.** Clean teeth mean that food particles won't be trapped in the device during the fitting process. If you have partial dentures, remove them.
- 2. Determine what type of bite you have.** When you close your jaw normally, do your upper front teeth overlap your lower front teeth? If so, you are like most people, and have a typical bite and should connect the upper and lower components of your PureSleep in the "neutral" setting, as described in the next step. Everyone else will use the "advanced" setting.
- 3. Attach the upper and lower parts of PureSleep in the setting that is best for you.** The upper and lower components of PureSleep are designed to fit together. The two plastic pins in the upper component fit into holes in the lower component in three possible positions, as shown on the next page.



6



NEUTRAL SETTING

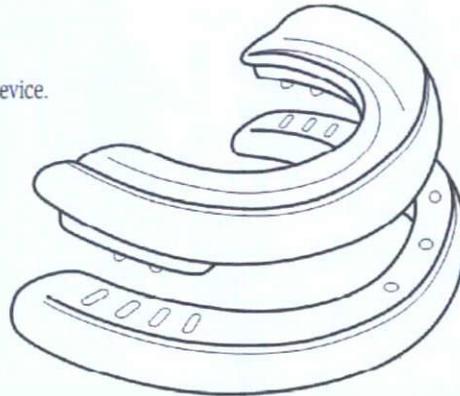
- Use the two holes closest to the front of the device.

ADVANCED SETTING

- Use the center two holes.

CUSTOM SETTING

- Use the two holes closest to the back.
Note: This setting should only be used if directed by a dentist.



www.puresleep.com

STOP
SNORING

Helpful hints, important tips.

HERE'S WHAT YOU WILL NEED:

- a medium size pot for heating one to two quarts of water
- a spatula, preferably slotted
- a timer with a second hand
- a toothbrush and toothpaste
- cuticle scissors
- a towel



PREVIEW OF THE FITTING PROCESS:

A timer with a second hand is critical to your success in fitting PureSleep. Here's how it's going to work...

- You will be heating the device in boiling hot water for one minute.
- Then you'll remove PureSleep from the water and wait 10 to 12 seconds for the device to cool.
- *While holding your jaw forward*, you must bite down hard to make an impression of your teeth in the softened plastic. You'll be holding that position for 30 seconds.

8

Common Mistakes to Avoid...

Fitting the PureSleep to your mouth is simple, but it's not quite as simple as it may seem. While you may be tempted to proceed without carefully reading the instructions, there are a number of details that can make a big difference. Here are the most common mistakes and how to avoid them:

- If you don't wait at least 10 seconds after removing PureSleep from the hot water, you can burn your mouth. But if you wait more than 12 seconds, the soft plastic will begin to harden and you won't get a deep enough impression of your teeth.
- Most people naturally tend to move their lower jaw backwards as they bite down. However, doing this will result in an improper fit, so you must resist this tendency. To ensure a proper fit, continue to hold your lower jaw forward while biting down.
- Don't be afraid to bite down hard. A deep impression will provide greater comfort and effectiveness.

Did you know...

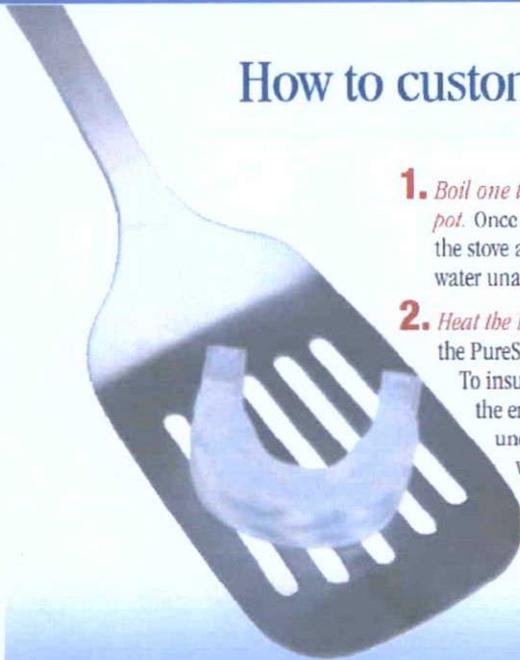
according to a recent National Sleep Foundation study, among those respondents who have a partner who snores, 38% mentioned having problems in their relationship due to sleep issues.

You are now ready to fit your PureSleep.

GO TO
SLEEP

How to custom-fit your PureSleep in

- 1. Boil one to two quarts of water in a medium size pot.** Once the water comes to a boil, remove it from the stove and turn off the burner. Do not leave boiling water unattended.
- 2. Heat the PureSleep.** Using the spatula, slowly lower the PureSleep into the pot of hot water for one minute. To insure that the hot water comes into contact with the entire device, use the spatula to hold the device under water. Avoid unnecessary movement, which can cause the two components to separate. If this happens, let the PureSleep cool for one minute and repeat this step.



10

www.puresleep.com

just minutes.

PureSleep[®]
The Stop Snoring Solution

3. *Fit the PureSleep to your mouth.* Hold the PureSleep out of the water with the spatula for exactly **10 to 12 seconds**. Then as quickly as possible, perform the following actions:

- Thrust your jaw forward as far as you comfortably can.
- Place the PureSleep in your mouth.
- *Continuing to hold your jaw forward*, bite down *very* firmly.

Important Note: Most people naturally tend to move their lower jaw backwards as they bite down. However, doing this will result in an improper fit, so you must resist this tendency.

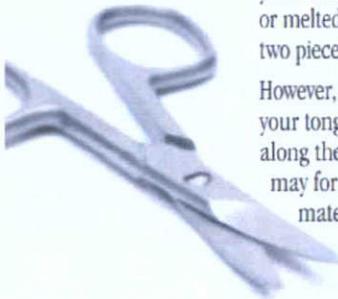
4. *Hold this position for 45 seconds.* Remove from your mouth and place the PureSleep under cool running tap water.

Note: It's normal for your teeth and gums to feel very warm during this process. If you are unable to maintain this position for the full 45 seconds, just hold it as long as you can.

STOP
SNORING

PureSleep[®]
The Stop Snoring Solution

5. *Trim away excess material for greater comfort.* Now that you have fitted your PureSleep, you may notice that some of the soft plastic has been fused or melted together. This is normal at both ends of the device as it holds the two pieces together.



However, some soft plastic may have been displaced and could interfere with your tongue and cause irritation. Excess plastic may have accumulated along the inner portions of the PureSleep. Also, sharp peaks of soft plastic may form during the fitting process. You should cut away any extra material using cuticle scissors.

Caution: For greater safety, fold your towel in half two or three times and use it to hold your PureSleep while trimming material.

6. *PureSleep works best if you have made a deep impression of your teeth in the soft plastic.* If you think that you have not achieved the best impression possible, simply repeat fitting steps 2 through 5. Try to avoid repeating these steps more than three or four times as it may weaken the PureSleep.

13

www.puresleep.com

Before you use your PureSleep...

- Brush your teeth.
- Remove partial dentures.
- Your PureSleep has been specifically prescribed to you and custom-fitted to your mouth. You should not let anyone else use your PureSleep.
- PureSleep works best if you sleep on your side or stomach. Specially designed pillows and "leg pillows" are available which can help you stay on your side during sleep.
- At first, some people have trouble sleeping with their PureSleep and some may even experience excess salivation or a slight "gagging" response. If this happens to you, make sure you have trimmed away any excess soft plastic, as described earlier. Also by placing your PureSleep in your mouth well in advance of going to bed, you can become acclimated to it before trying to sleep.
- If you wake up in the middle of the night and are bothered by your PureSleep, just take it out and go back to sleep. Each night, you should be able to sleep longer with your PureSleep, and in just a few nights, you should be sleeping snorelessly through the entire night!



What to expect the next morning...

It's normal for your jaw, teeth, and gums to feel moderately sore and fatigued for the first three to five mornings as you acclimate to the new position during sleep. Also, if you don't use your PureSleep for several days, you may need to "re-acclimate" yourself.

⚠ Caution: It is not normal to experience severe, sharp pain or for your jaw to suddenly become more limited in its ability to open. These symptoms may be an indication of a serious problem with the main joint of your jaw, called temporomandibular disorder (TMD). Additional symptoms of TMD include clicking or popping sounds when moving your jaw. If you experience these symptoms or believe that you may have TMD, discontinue use immediately and contact ThePure Sleep Company for a full refund per the terms of the PureSleep 30 day money-back guarantee. If these symptoms persist, you should contact your dentist or physician. Likewise, discontinue use if your snoring becomes worse, you have difficulty breathing while using your PureSleep, or you experience ongoing pain in your teeth or gums.

How to get used to the *forward* position.



Morning exercise: Gently push your jaw backwards, relax your muscles and hold for about a minute.

Each morning, your jaw will tend to stay in a "forward" position after the PureSleep is removed because the muscles in your jaw have become used to this position during the night. This is normal and is no cause for alarm. Within two to three hours, your jaw should return to its normal position.

You can also significantly shorten this time by performing a simple "jaw stretching" exercise in which you gently push your jaw backwards while relaxing the muscles in your jaw and holding this position for about a minute.

⚠ Caution: If your jaw does not return to its normal position or if you experience any movement of your teeth, discontinue use and contact The Pure Sleep Company for a full refund per the terms of the PureSleep 30 day money-back guarantee. If symptoms persist, contact your dentist or physician.

STOP
SNORING

Taking care of your PureSleep:

- Be sure to store PureSleep in a cool, dry place.
- Periodically, clean PureSleep with a toothbrush and toothpaste, or soak in water with effervescent oral device cleaning tablets.
- Do not use harsh chemicals or household cleaning products like bleach or ammonia.

PureSleep
The Stop Snoring Solution

Questions?

Call 866-879-3777
Monday through Friday,
8:30 am to 10:00 pm
Eastern Time
Individual results may vary.



Take care of your PureSleep and PureSleep will take care of you. Remember to clean according to instructions (at left). Now go to sleep!

PureSleep is proudly made in the United States from American-sourced materials. Patent No. 5,499,655

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Attachment 4.2

Revised Draft SnoreRx Instruction For Use

Instructions for Use

SnoreRx_x

MouthGuard



INSTRUCTIONS FOR CARE & USE [21 CFR 80787(e)]

SnoreRx is an intraoral appliance designed to reduce, or eliminate snoring by keeping the patient's airway open. It is not intended to treat any health, or clinical condition. If the patient believes they may have a health issue such as sleep apnea they should consult their healthcare professional immediately.

DO NOT USE SNORERX IF:

- You have been diagnosed with central sleep apnea. SnoreRx is not a treatment for sleep apnea or any other medical condition.
- You have chronic asthma, emphysema, or any other severe respiratory disorder. If you have a history of any of these diseases, consult a physician prior to use.
- You have loose teeth, abscesses, or severe gum disease.
- You are less than 18 years of age.
- You have had a dental implant within the last year.
- You have been diagnosed with temporomandibular disorder (TMD), which is a disease of the "jaw joint", unless a dentist or physician has advised you that you may use SnoreRx.
- You have full dentures or are undergoing orthodontic treatment.
- The package seal was broken when you received your SnoreRx.

If you are unable to use your SnoreRx for any of these reasons, please return it for a refund per the terms of the SnoreRx 30 day money-back guarantee.

CONTRAINDICATIONS

The SnoreRx is contraindicated in:

- Patients with sleep apnea, OSA.
- Patients under the age of 18
- Patients with a history of TMD, temporomandibular disorder
- Patients who have had teeth implants within the past year
- Patients who wear dentures
- Patients with loose teeth, abscesses, or severe gum disease
- Patients undergoing orthodontic treatment
- Patients with chronic asthma, emphysema, or any respiratory disorder

WARNINGS

Use of SnoreRx may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Excessive salivation

CUSTOM FITTING INSTRUCTIONS

Materials required for custom fitting are:

- Timer with second hand
- A small pot for heating two quarts of boiling water
- A towel
- A spatula, or tongs

CUSTOM FITTING PROTOCOL

1. Boil two quarts of water, remove the pot from the stove and turn off the stove. Do not leave boiling water unattended.
2. Using the spatula or tongs to submerge the SnoreRx into the boiled water for precisely **90 SECONDS** and then remove from the boiled water.
3. **Very quickly** dry SnoreRx with a paper towel to remove any water.
4. **Important** – Immediately (within 10 seconds) after removing SnoreRx from the boiled water, place it in the patient's mouth (in the 0 advancement position) to bite down firmly for **30 SECONDS**. **Note:** It is recommended that the patient's teeth be brushed and flossed before the fitting.
5. Remove SnoreRx from the mouth and put it in a bowl of ice water for **60 SECONDS** to set the impression. **Note:** SnoreRx works best with a deep impression of the teeth. If this does not occur repeat steps 1, 2, 3 and 4.
6. Advance and set the lower jaw piece to 4-5mm, whichever is more comfortable. This is best done by clicking forward and rocking backward the lower jaw piece as desired. **DONE!** [Future adjustments may be made as required]

Before you use your SnoreRx:

Brush your teeth.

- Remove partial dentures.
- Your SnoreRx has been custom-fitted to your mouth. You should not let anyone else use your SnoreRx.
- SnoreRx works best if you sleep on your side or stomach. Specially designed pillows and "leg pillows" are available which can help you stay on your side during sleep.
- At first, some people have trouble sleeping with their SnoreRx and some may even experience excess salivation. Also by placing your SnoreRx in your mouth well in advance of going to bed, you can become acclimated to it before trying to sleep.
- If you wake up in the middle of the night and are bothered by your SnoreRx, just take it out and go back to sleep. Each night, you should be able to sleep longer with your SnoreRx, and in just a few nights, you should be sleeping with reduced snoring through the entire night!

USER INSTRUCTIONS

- SnoreRx should be worn for 1-3 hours for the first 2 days. This helps to acclimate your mouth to wearing it.
- It is common to have a dry mouth and for your jaw, teeth and gums to feel tender during initial use of SnoreRx.
- SnoreRx can be adjusted forwards or backwards to both maximize comfort and reduce snoring. This can be done by clicking the lower jaw piece of SnoreRx forward or rocking it backward to the desired position. Most snoring can be reduced with a setting between 4-7mm.

CARE & HANDLING

- Store SnoreRx in its case in a cool dry place.
- Periodically, clean SnoreRx with a toothbrush and toothpaste.
- Do not use harsh chemicals or household cleaning products like bleach or ammonia.

CAUTION

If you experience prolonged discomfort, bleeding, loose or moving teeth, excess jaw pain, limited jaw movement, bite changes or other problems that may be associated with using SnoreRx immediately discontinue use and contact your dentist or physician for advice. Also contact Consumer Health Products for a refund according to company policy.

QUESTIONS

Consumer Health Products, Inc.

1 Brownsbury Road

Laguna Niguel, Ca. 92677

Email: customerservice@snorerx.co

Phone: (949) Snorerx (766-7379)

Attachment 5

Revised Sections from original submission

Redlined portion of Section 12 from Original Submission

Section 12

Device Description

12. Device Description

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce or eliminate snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The common term for these types of devices is a Mandibular Adjusting Device (MAD). The device consists of two custom fabricated trays (constructed with a material to allow for customizing teeth impression) that fit separately over the upper and lower dental arches, and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep.

SnoreRx NS 9.0

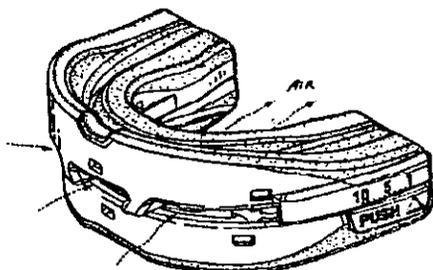


Fig.

This schematic provides a detailed description of the SnoreRx NS 9.0. The arrows in the front illustrate the airway channels that facilitate mouth breathers. The engraved word "PUSH" serves to unlock the lower tray for resetting. The gradient scale, "10-5-1" records the setting that corresponds to the relative repositioning distance selected for quick future reference.

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Revised portion of Section 12 from Original Submission

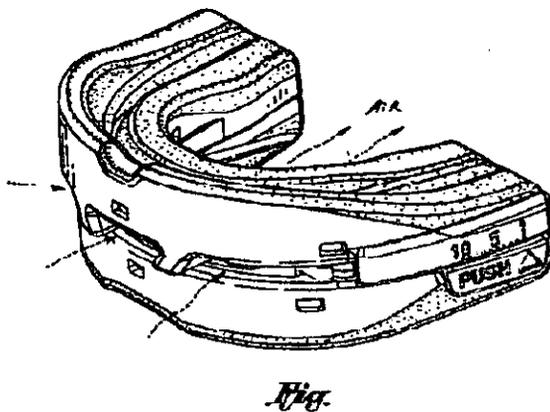
Section 12

Device Description

12. Device Description

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The common term for these types of devices is a Mandibular Adjusting Device (MAD). The device consists of two custom fabricated trays (constructed with a material to allow for customizing teeth impression) that fit separately over the upper and lower dental arches, and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep.

SnoreRx NS 9.0



This schematic provides a detailed description of the SnoreRx NS 9.0. The arrows in the front illustrate the airway channels that facilitate mouth breathers. The engraved word "PUSH" serves to unlock the lower tray for resetting. The gradient scale, "10-5-1" records the setting that corresponds to the relative repositioning distance selected for quick future reference.

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Redlined portion of Section 11 from Original Submission

(b)(4) Draft



(b)(4) Draft



Revised portion of Section 11 from Original Submission

Section 11

Executive Summary

11. Executive Summary

Executive Summary

Device Description

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce snoring by advancing the lower jaw and thereby minimizing. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep.

Intended Use

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Predicate Devices

The Consumer Health Products "SnoreRx NS 9.0" is substantially equivalent in intended use, principal of operation and technological characteristics to the typical devices cleared under Product Code LRK as well as those listed below. A summary of the substantial equivalence between the Consumer Health Products "SnoreRx NS 9.0" and the predicates is found in the table below.

Substantial Equivalence Table

Product	Intended Use	Principle of Operation	Overall Technological Characteristics
Consumer Health Products SnoreRx NS 9.0	The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	Provides for mandibular repositioning to increase pharyngeal space	Custom fitted plastic intraoral device inserted over the upper and lower dental arches.
SnoreGuard (K103004)	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	SAME	SAME
Silencer (K954530)	Intended to reduce or eliminate night time snoring in patients 18 years of age or older only.	SAME	SAME
SnoreControl (K963591)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME

Consumer Health Products, Inc
 SnoreRx NS 9.0

Premarket Notification

Section 11

Executive Summary

Performance Testing

Performance testing was conducted for the Consumer Health Products SnoreRx NS 9.0 to demonstrate the integrity and suitability of the device for its intended use. The results of the testing indicate that the Consumer Health Products SnoreRx NS 9.0 C is substantially equivalent to the predicate devices and is safe and effective for its intended use.

Attachment for Item 6.1

Material Characterization Test Results

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

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Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Attachments for Item 7

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

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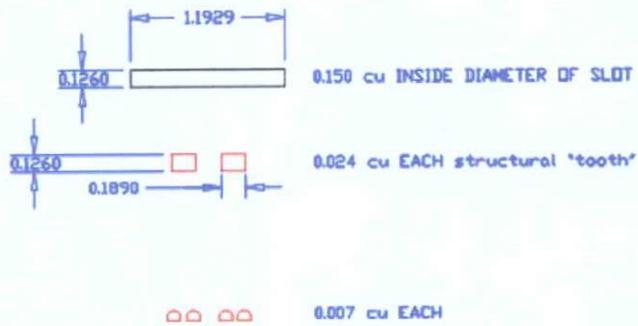
Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Records processed under FOIA Request # 2015-4518; Released by CDRH on 11-30-2015

Attachment for Item 8

Comparison of airway passages for mouth breathers

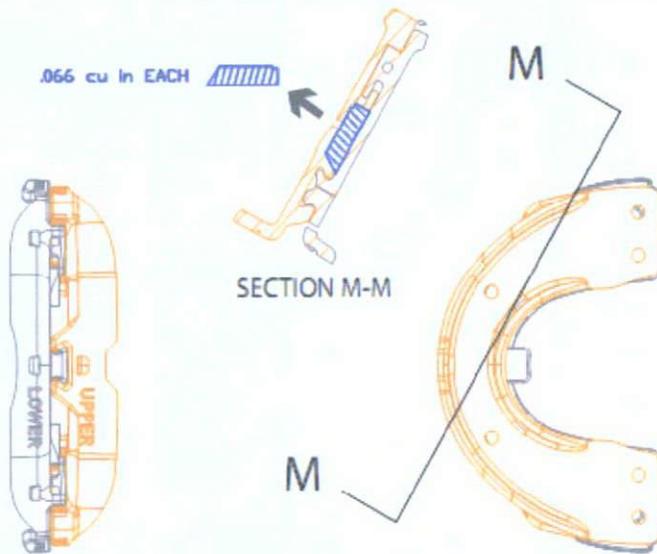
PURESLEEP



0.150 cu in gross measurement
- 0.048 square 'teeth' (0.024 x 2)

0.102 cu in net airflow
- 0.028 rounded 'teeth' (0.007 x 4)

SnoreRX



0.066 measurement

x2

0.132 cu in net airflow

SUMMARY: The airway channel of the SnoreRx compares very favorably with the predicate device. There is therefore sufficient airflow for full mouth breathers while sleeping.

Attachment for Item 9

Revised from original submission

Section 13

Substantial Equivalence Discussion

Comparison of Predicate Devices

[807.92(a)(5)]

Attribute	SnoreRx	SomnoGuard K060502K103004	Silencer K954530	SnoreControl K963591
Year FDA Cleared		2006	1995	1997
Use:				
Intended as an intraoral device	Yes	Yes	Yes	Yes
Intended to reduce or help alleviate snoring	Yes	Yes	Yes	Yes
Indicated for use with persons who snore	Yes	Yes	Yes	Yes
Indicated for single user	Yes	Yes	Yes	Yes
Indicated for use at home	Yes	Yes	Yes	Yes
Design:				
"Boil & Bite" material for fitting	Yes	Yes	Yes	Yes
Can be adjusted	Yes	Yes	Yes	Yes
Permits User to breath through mouth & nose	Yes	Yes	No	Yes
Fixed and stable retention	Yes	Yes	No	Yes
Designed with upper and lower tray	Yes	Yes	No	Yes
Custom for each user	Yes	Yes	Yes	Yes
Incorporates alignment for proper fitting	Yes	Yes	Yes	Yes
Placed in users mouth each evening	Yes	Yes	Yes	Yes
Cleaned daily	Yes	Yes	Yes	Yes
Easily removed from mouth	Yes	Yes	Yes	Yes
Sanitized when boiled	Yes	Yes	Yes	Yes
Materials:				
Non Sterile	Yes	Yes	Yes	Yes
Heat Sensitive Moldable	Yes	Yes	Yes	Yes
Health Grade Copolymer Plastic BPA FREE	Yes	Yes	Yes	Yes

Consumer Health Products, Inc
 SnoreRx NS 9.0

Premarket Notification

Revised Substantial Equivalency Tables

Attribute	[807.92(a)(5)]					SnoreMaster
	SnoreRx	SomnoGuard K103004	Silencer K954530	SnoreControl K963591	PureSleep K954128	
Year FDA Cleared		2006	1995	1997		1995
Use:						
Intended as an intraoral device	Yes	Yes	Yes	Yes		Yes
Intended to reduce or help alleviate snoring	Yes	Yes	Yes	Yes		Yes
Indicated for use with persons who snore	Yes	Yes	Yes	Yes		Yes
Indicated for single user	Yes	Yes	Yes	Yes		Yes
Indicated for use at home	Yes	Yes	Yes	Yes		Yes
Design:						
"Boil & Bite" material for fitting	Yes	Yes	Yes	Yes		Yes
Can be adjusted	Yes	Yes	Yes	Yes		Yes
Permits User to breath through mouth & nose	Yes	Yes	No	Yes		Yes
Fixed and stable retention	Yes	Yes	No	Yes		Yes
Designed with upper and lower tray	Yes	Yes	No	Yes		Yes
Custom for each user	Yes	Yes	Yes	Yes		Yes
Incorporates alignment for proper fitting	Yes	Yes	Yes	Yes		Yes
Placed in users mouth each evening	Yes	Yes	Yes	Yes		Yes
Cleaned daily	Yes	Yes	Yes	Yes		Yes
Easily removed from mouth	Yes	Yes	Yes	Yes		Yes
Sanitized when boiled	Yes	Yes	Yes	Yes		Yes
Materials:						
Non Sterile	Yes	Yes	Yes	Yes		Yes
Heat Sensitive Moldable	Yes	Yes	Yes	Yes		Yes

PERFORMANCE DATA EQUIVALENCE					
Performance Standard	SnoreRx	SomnoGuard	Silencer	SnoreControl	SnoreMaster
Design - provides adequate air channel	two in front	central channel	front channel	front channel	front channel
Design - incorporates alignment feature	Yes	Yes	Yes	Yes	Yes
Design - setting may be changed and reset	Yes	Yes - screw	Yes - Plate	Yes - Velcro	Yes
Design - Employs two trays - upper / lower	Yes	Yes	Yes	Yes	Yes
Offers custom thermal fit	Yes	Yes	Yes	Yes	Yes
Locking mechanism to maintain advancement	Yes	Yes - Bolt/screw	Yes - plate	Yes - Velcro	Yes
Ability to micro adjust advancement	Yes	Yes	Yes	Yes	Yes
Material - Health grade thermoplastic	Yes	Yes	Yes	Yes	Identical to proposed

Attachment for Item 10

No additional information required to support response

Attachment for Item 11

Attachment for Item 12
Redlines of Section 6 of Original Submission

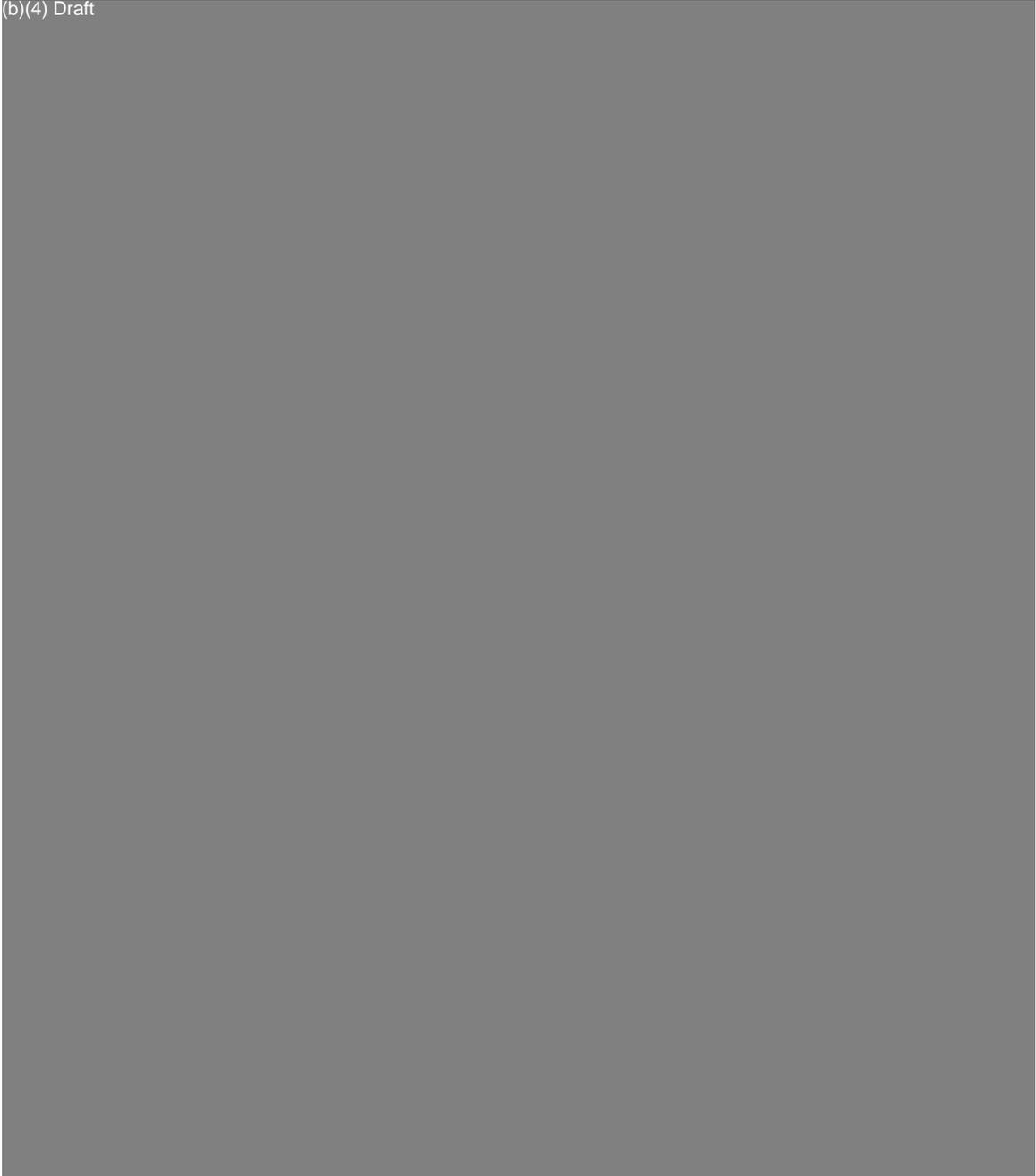
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(b)(4) Draft



Revised Section 6 (510(k) Summary)

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: Consumer Health Products, Inc.
17 Brownsbury Road #110
Laguna Niguel, CA 92677

CONTACT : Gary Mocnik
49 Coastal Oak, Aliso Viejo, CA 92656
949.433.0413
949.831.9944 fax
gmocnik@cox.net

DATE PREPARED July 25, 2011

TRADE NAME: SnoreRx NS 9.0

COMMON NAME: Anti-Snoring Mouth Piece

CLASSIFICATION NAME: Anti-Snoring Device, 21 CFR, 872.5570

DEVICE CLASSIFICATION: Class II

PRODUCT CODE LRK

PREDICATE DEVICES: SnoreGuard (K103004), Silencer (K954530), SnoreControl (K963591), SnoreMaster (K954128)

Substantially Equivalent To:

The Consumer Health Products SnoreRx NS 9.0 is substantially equivalent in intended use, principal of operation and technological characteristics to the SnoreGuard (K103004), the Silencer (K954530), the SnoreControl (K963591), and the SnoreMaster (K954128), as well as other predicate devices cleared with an LRK Product Code.

Description of the Device Subject to Premarket Notification:

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep

Indication for Use:

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Discussion of Technological Characteristics:

The Consumer Health Products SnoreRx NS 9.0 has similar physical and technical characteristics to the predicate devices. The Consumer Health Products SnoreRx NS 9.0 and the identified predicates all provide means for advancing the lower jaw in a predetermined manner. The technical designs and manufacture of the SnoreRx NS 9.0 and the predicate devices are very similar, being composed of custom fitted acrylic trays which fit onto the upper and lower teeth and which are positioned in relation to each other by an adjustable mechanism.

Non-Clinical Performance Data:

Performance testing was conducted to evaluate and characterize the performance of the Consumer Health Products SnoreRx NS 9.0. Preclinical testing conducted included dimensional conformance evaluation, visual inspections, design verification testing to confirm airway passage equivalency, and biocompatibility testing of device materials based on the applicable elements of ISO 10993-1 shown below.

Test Performed	Standard	Test Result/Conclusion
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	ISO 10993-5	Passed. Non-cytotoxic
ISO Intracutaneous Irritation Test	ISO 10993-10	Passed. Non-irritant
Sensitization: Guinea Pig Maximization	ISO 10993-10	Passed/Negative for evidence of sensitization

Additionally material characterization testing was performed and concluded that the materials used in the construction of the Consumer Health Products SnoreRx NS 9.0 are identical the a listed predicate device.

Clinical Data

This submission does not rely on clinical data to determine substantial equivalency to the predicate devices.

Basis for Determination of Substantial Equivalence:

The following table displays the differences and similarities between the new SnoreRx NS 9.0 and other previously marketed devices.

Product	Intended Use	Principle of Operation	Overall Technological Characteristics
Consumer Medical Products SnoreRx NS 9.0	The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	Provides for mandibular repositioning to increase pharyngeal space	Custom fitted plastic intraoral device inserted over the upper and lower dental arches.
SnoreGuard (K103004)	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	SAME	SAME
Silencer	Intended to reduce or eliminate night time snoring	SAME	SAME

(K954530)	in patients 18 years of age or older only.		
SnoreControl (K963591)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME
SnoreMaster (9541285)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME

Conclusions Drawn

As shown, the Consumer Health Products SnoreRx NS 9.0 has the following similarities to the predicate devices:

- Same intended use
- Same design characteristics
- Same operating principal
- Same mechanism of action
- Same technological characteristics

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Consumer Health Products SnoreRx NS 9.0 is determined to be substantially equivalent to existing legally marketed devices, performs as well as the predicate devices, and is as safe and effective for its intended use.

END OF SUBMISSION

465

K112205/S2

**Gary S. Mocnik & Associates
Regulatory Consultants
49 Coastal Oak
Aliso Viejo, California 92656
949-433-0413**

November 4, 2011

FDA CDRH DMC

NOV 07 2011

Received

Ms. Sheena Green
Food and Drug Administration
Center for Device and Radiological Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: SnoreRx NS 9.0 (K112205/S1)
Response to email communication dated 11-01-2011

Dear Ms. Green,

Thank you for your efforts in reviewing this premarket notification. The following is in response to your email communication dated November 1, 2011 requesting additional information regarding the above referenced submission. The FDA request is repeated in italics followed by the company's response.

We believe that these responses adequately address the issues raised by the agency and are adequate to determine substantial equivalency to the predicate devices.

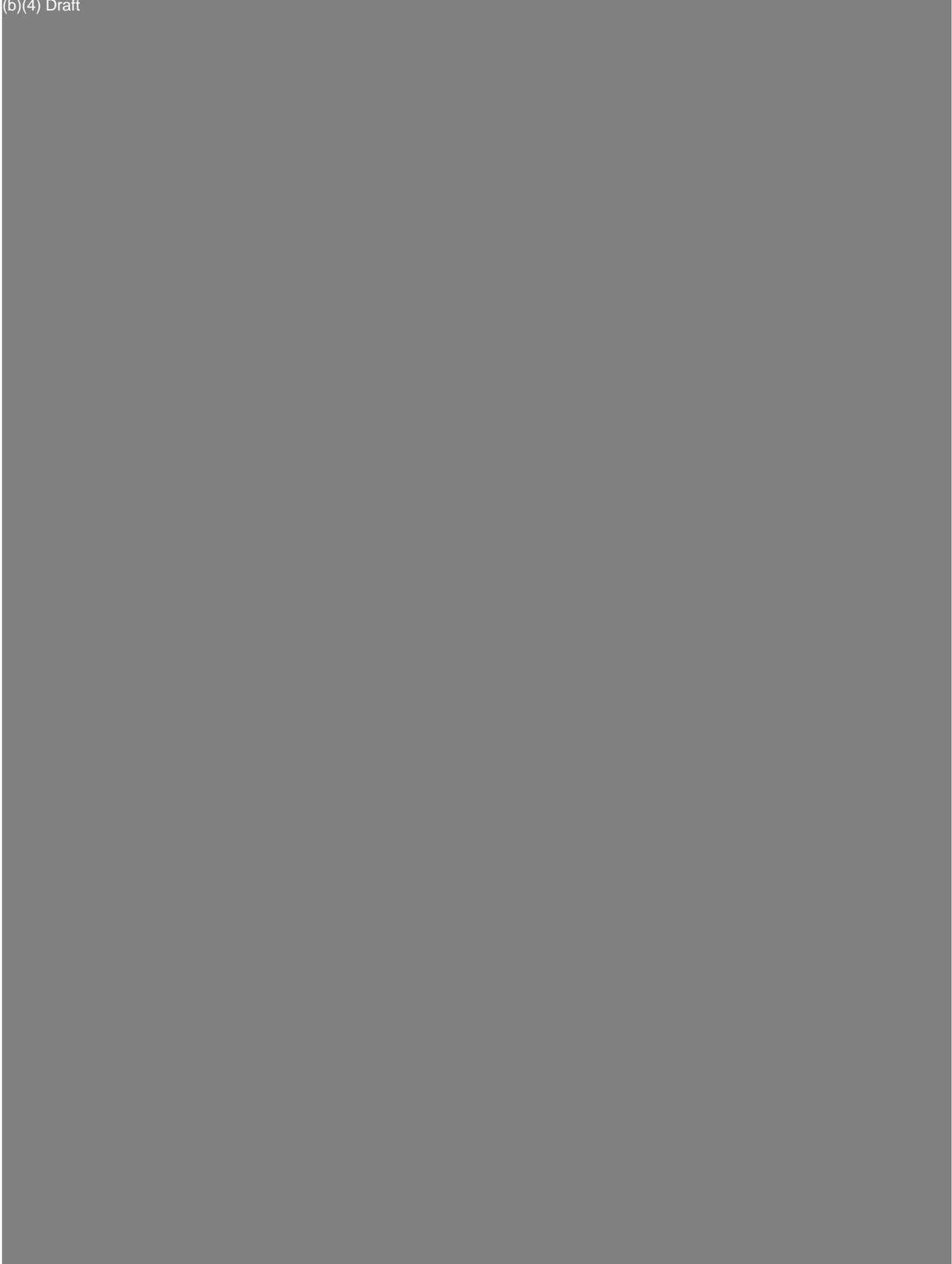
Thank you for your consideration of this response. If you have any questions or need any further information, please contact me at (949) 433-0413.

Sincerely,

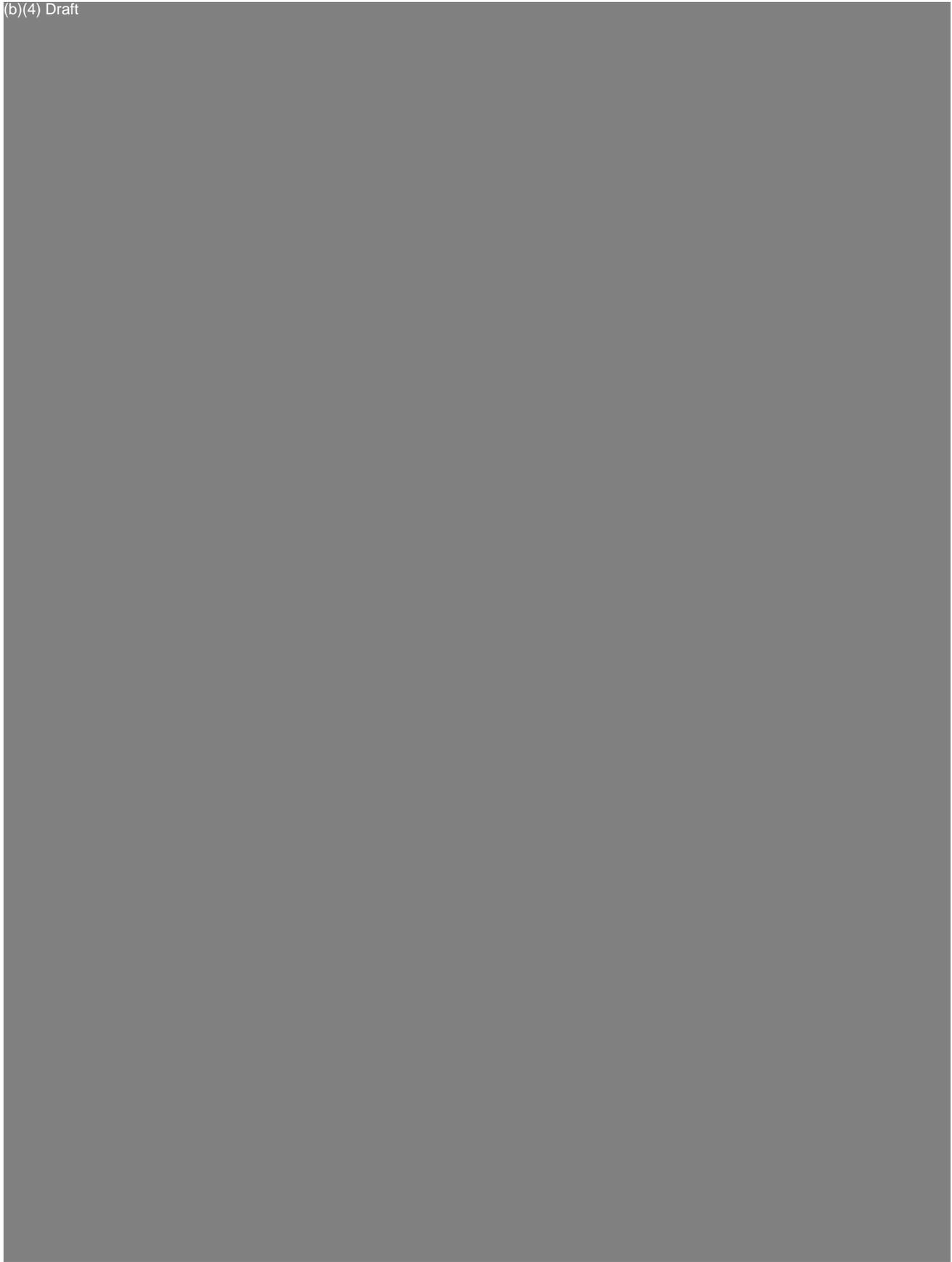


Gary S. Mocnik
Official Correspondent for Consumer Health Products

(b)(4) Draft



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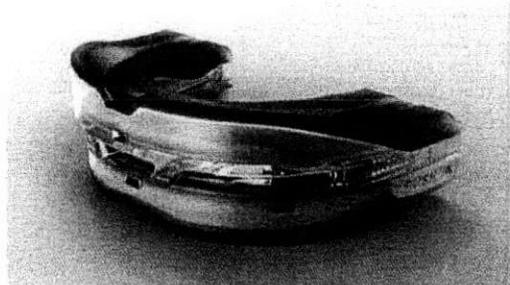
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**Attachments for Item 1
(Revised Instructions For Use)**

Instructions for Use

SnoreRx_x **MouthGuard**



INSTRUCTIONS FOR CARE & USE **[21 CFR 80787(e)]**

SnoreRx is an intraoral appliance designed to reduce snoring by keeping the patient's airway open. It is not intended to treat any health, or clinical condition. If the patient believes they may have a health issue such as sleep apnea they should consult their healthcare professional immediately.

INDICATIONS FOR USE:

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

DO NOT USE SNORERX IF:

- You have been diagnosed with central sleep apnea. SnoreRx is not a treatment for sleep apnea or any other medical condition.
- You have chronic asthma, emphysema, or any other severe respiratory disorder. If you have a history of any of these diseases, consult a physician prior to use.
- You have loose teeth, abscesses, or severe gum disease.
- You are less than 18 years of age.
- You have had a dental implant within the last year.
- You have been diagnosed with temporomandibular disorder (TMD), which is a disease of the "jaw joint", unless a dentist or physician has advised you that you may use SnoreRx.
- You have full dentures or are undergoing orthodontic treatment.
- The package seal was broken when you received your SnoreRx.
- If you are unable to use your SnoreRx for any of these reasons, please return it for a refund per the terms of the SnoreRx 30 day money-back guarantee.

WARNINGS

Use of SnoreRx may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Excessive salivation

CUSTOM FITTING INSTRUCTIONS (*SnoreRx is to be fitted by or under the direction of a dentist or licensed medical practitioner*)

Materials required for custom fitting are:

- Timer with second hand
- A small pot for heating two quarts of boiling water
- A towel
- A spatula, or tongs

CUSTOM FITTING PROTOCOL

1. Boil two quarts of water, remove the pot from the stove and turn off the stove. Do not leave boiling water unattended.
2. Using the spatula or tongs to submerge the SnoreRx into the boiled water for precisely **90 SECONDS** and then remove from the boiled water.
3. **Very quickly** dry SnoreRx with a paper towel to remove any water.
4. **Important** – Immediately (within 10 seconds) after removing SnoreRx from the boiled water, place it in the patient's mouth (in the 0 advancement position) to bite down firmly for **30 SECONDS**. **Note:** It is recommended that the patient's teeth be brushed and flossed before the fitting.
5. Remove SnoreRx from the mouth and put it in a bowl of ice water for **60 SECONDS** to set the impression. **Note:** SnoreRx works best with a deep impression of the teeth. If this does not occur repeat steps 1, 2, 3 and 4.
6. Advance and set the lower jaw piece to 4-5mm, whichever is more comfortable. This is best done by clicking forward and rocking backward the lower jaw piece as desired. **DONE!** [Future adjustments may be made as required]

BEFORE YOU USE YOUR SnoreRx:

Brush your teeth.

- Remove partial dentures.
- Your SnoreRx has been custom-fitted to your mouth. You should not let anyone else use your SnoreRx.
- SnoreRx works best if you sleep on your side or stomach. Specially designed pillows and "leg pillows" are available which can help you stay on your side during sleep.
- At first, some people have trouble sleeping with their SnoreRx and some may even experience excess salivation. Also by placing your SnoreRx in your mouth well in advance of going to bed, you can become acclimated to it before trying to sleep.
- If you wake up in the middle of the night and are bothered by your SnoreRx, just take it out and go back to sleep. Each night, you should be able to sleep longer with your SnoreRx, and in just a few nights, you should be sleeping with reduced snoring through the entire night!

USER INSTRUCTIONS

- SnoreRx should be worn for 1-3 hours for the first 2 days. This helps to acclimate your mouth to wearing it.
- It is common to have a dry mouth and for your jaw, teeth and gums to feel tender during initial use of SnoreRx.
- SnoreRx can be adjusted forwards or backwards to both maximize comfort and reduce snoring. This can be done by clicking the lower jaw piece of SnoreRx forward or rocking it backward to the desired position. Most snoring can be reduced with a setting between 4-7mm.

CARE & HANDLING

- Store SnoreRx in its case in a cool dry place.
- Periodically, clean SnoreRx with a toothbrush and toothpaste.
- Do not use harsh chemicals or household cleaning products like bleach or ammonia.

CAUTION

If you experience prolonged discomfort, bleeding, loose or moving teeth, excess jaw pain, limited jaw movement, bite changes or other problems that may be associated with using SnoreRx immediately discontinue use and contact your dentist or physician for advice. Also contact Consumer Health Products for a refund according to company policy.

QUESTIONS

Consumer Health Products, Inc.

1 Brownsbury Road

Laguna Niguel, Ca. 92677

Email: customerservice@snorerx.co

Phone: (949) Snorerx (766 -7379)

Attachment for Item 2

See Attachment 1

42

Attachment for Item 3
(Material Certification Statement)

Certification Statement

The combination of raw materials that make up the final product known as SnoreRx, is identical to the finished predicate product known as Pure Sleep. Therefore, it can be concluded that SnoreRx shares the same biocompatibility with the predicate device known as Pure Sleep.

Additionally, Pursuant to 21 CFR 807.87(j), I certify that in my capacity as President of Consumer Health Products, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.


James Fallon
Consumer Health Products, Inc.
A Division of ASC

11-4-2011

Attachments for Item 5

(Click link below for full versions of attached forms)



3654 combined.pdf

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-10 Biological Evaluation of Medical Device- Part 10 Tests for Irritation (2002)		
<i>Please answer the following questions</i>		
Is this standard recognized by FDA ² ?	Yes	No
.....	✓	—
FDA Recognition number ³	# 02-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: G-95 Blue Book Memorandum: Use of ISO 10993-1		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/rdmt/aprog.html</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cdoci/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or</p> </div> <div style="width: 45%;"> <p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cdoci/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p> </div> </div>		

46

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-10 Biological Evaluation of Medical Device- Part 10 Tests for Irritation (2002)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All	SECTION TITLE All	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* See attached description of compliance located in this 510k submission		
DESCRIPTION See attached description of compliance located in this 510k submission		
JUSTIFICATION See attached description of compliance located in this 510k submission		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
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TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-5 Biological Evaluation of Medical Device- Part 5 Tests for In Vitro Cytotoxicity (2009)		
<i>Please answer the following questions</i>		
Is this standard recognized by FDA? ²	Yes	No
.....	✓	—
FDA Recognition number ³	# 02-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	✓	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	✓
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	✓	<input type="checkbox"/>
Does this standard include acceptance criteria?	✓	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	✓	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	✓
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	✓
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	✓
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	✓
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Is there an FDA guidance ⁶ that is associated with this standard?	✓	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510(k)?	✓	<input type="checkbox"/>
Title of guidance: G-95 Blue Book Memorandum: Use of ISO 10993-1		
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CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All	SECTION TITLE All	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* See attached description of compliance located in this 510k submission		
DESCRIPTION See attached description of compliance located in this 510k submission		
JUSTIFICATION See attached description of compliance located in this 510k submission		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p align="center">Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p align="center">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p align="center"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

Attachment for Item 6
IFU form

Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: SnoreRx NS 9.0

Indications for Use:

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use _____
(Optional Format 1-2-96)

Page __ of __

Attachment for Item 6
(Revised 510(k) Summary)

Section 6

510(k) Summary

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: Consumer Health Products, Inc.
17 Brownsbury Road #110
Laguna Niguel, CA 92677

CONTACT : Gary Mocnik
49 Coastal Oak, Aliso Viejo, CA 92656
949.433.0413
949.831.9944 fax
gmocnik@cox.net

DATE PREPARED July 25, 2011

TRADE NAME: SnoreRx NS 9.0

COMMON NAME: Anti-Snoring Mouth Piece

CLASSIFICATION NAME: Anti-Snoring Device, 21 CFR, 872.5570

DEVICE CLASSIFICATION: Class II

PRODUCT CODE LRK

PREDICATE DEVICES: SnoreGuard (K103004), Silencer (K954530), SnoreControl (K963591), SnoreMaster (K954128)

Substantially Equivalent To:

The Consumer Health Products SnoreRx NS 9.0 is substantially equivalent in intended use, principal of operation and technological characteristics to the SnoreGuard (K103004), the Silencer (K954530), the SnoreControl (K963591), and the SnoreMaster (K954128), as well as other predicate devices cleared with an LRK Product Code.

Description of the Device Subject to Premarket Notification:

The Consumer Health Products SnoreRx NS 9.0 is an intraoral device used at night to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Section 6**510(k) Summary****Indication for Use:**

The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Discussion of Technological Characteristics:

The Consumer Health Products SnoreRx NS 9.0 has similar physical and technical characteristics to the predicate devices. The Consumer Health Products SnoreRx NS 9.0 and the identified predicates all provide means for advancing the lower jaw in a predetermined manner. The technical designs and manufacture of the SnoreRx NS 9.0 and the predicate devices are very similar, being composed of custom fitted acrylic trays which fit onto the upper and lower teeth and which are positioned in relation to each other by an adjustable mechanism.

Non-Clinical Performance Data:

Performance testing was conducted to evaluate and characterize the performance of the Consumer Health Products SnoreRx NS 9.0. Preclinical testing conducted included dimensional conformance evaluation, visual inspections, design verification testing to confirm airway passage equivalency, and biocompatibility testing of device materials based on the applicable elements of ISO 10993-1 shown below.

Test Performed	Standard	Test Result/Conclusion
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	ISO 10993-5	Passed. Non-cytotoxic
ISO Intracutaneous Irritation Test	ISO 10993-10	Passed. Non-irritant
Sensitization: Guinea Pig Maximization	ISO 10993-10	Passed/Negative for evidence of sensitization

Additionally material characterization testing was performed and concluded that the materials used in the construction of the Consumer Health Products SnoreRx NS 9.0 are identical the listed predicate device.

Clinical Data

This submission does not rely on clinical data to determine substantial equivalency to the predicate devices.

Basis for Determination of Substantial Equivalence:

The following table displays the differences and similarities between the new SnoreRx NS 9.0 and other previously marketed devices.

Product	Intended Use	Principle of Operation	Overall Technological Characteristics
Consumer Medical	The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age	Provides for mandibular	Custom fitted plastic intraoral

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

Section 6**510(k) Summary**

Products SnoreRx NS 9.0	or older as an aid for the reduction of snoring.	repositioning to increase pharyngeal space	device inserted over the upper and lower dental arches.
SnoreGuard (K103004)	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	SAME	SAME
Silencer (K954530)	Intended to reduce or eliminate night time snoring in patients 18 years of age or older only.	SAME	SAME
SnoreControl (K963591)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME
SnoreMaster (9541285)	The anti-snoring device is intended to alleviate or correct snoring	SAME	SAME

Conclusions Drawn

As shown, the Consumer Health Products SnoreRx NS 9.0 has the following similarities to the predicate devices:

- Same intended use
- Same design characteristics
- Same operating principal
- Same mechanism of action
- Same technological characteristics

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Consumer Health Products SnoreRx NS 9.0 is determined to be substantially equivalent to existing legally marketed devices, performs as well as the predicate devices, and is as safe and effective for its intended use.

Consumer Health Products, Inc
SnoreRx NS 9.0

Premarket Notification

55

END OF SUBMISSION