K150572

Quality Solutions & Support

Quality Success... is the ability to improve with knowledge

143

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Special 510(k) Notification (21 CFR 807.90(e)) for Respire Pink Series – Herbst - EF

Dear Reviewer,

The following Special 510(k) is submitted in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Respire Medical, LLC proposes to introduce into interstate commerce, for commercial distribution the Pink Series – Herbst - EF.

This submission contains methods, data and analysis of these data which the Sponsor considers "Trade Secret", commercially privileged and confidential. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act. In accordance with 21 CFR §807.95; the submitter considers their intent to market the device to be confidential commercial information.

The Respire Pink Series – Herbst was previously cleared in K131138. The only modification to the device since its previous clearance is that the end -user now has an option to select a chrome (Wironit material) along with the original Acrylic material used to create the device plates. This modification represent a minor device modification and do not affect the indications for use and are therefore appropriate for a Special 510(k).

Class II Special Controls Guidance Document: Intraoral Devices for Snoring and / or Obstructive Sleep Apnea; Guidance for Industry and FDA was reviewed.

An eCopy is provided with this submission and is an exact duplicate of the original paper submission.

The following submission details are provided in accordance with FDA Guidance documents

Device Common Name: Device, Anti-Snoring

143

Stephen W. Inglese -
CEO/Founder
561.201.8870
swi@qss-llc.com

Main Office
954.830.0051
info@qss-llc.com

Device Proprietary Name: Respire Pink Series – Herbst - EF

Submitter: Respire Medical, LLC
18 Bridge St Ste 4J
Brooklyn, NY 10021
Phone: 718-643-7326

Contact: Stephen Inglese
Consultant
Quality Solutions and Support, LLC
Phone: 561-251-0876
Email: swi@qss-llc.com

Classification Regulation: 21 CFR §872.5570, Class II – Device Anti-Snoring
Panel: Dental
Product Code: LRK

Design and Use of Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?[A]		X
Does the device contain components derived from a tissue or other 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
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Please do not hesitate to contact me at any time during the review process to answer questions or provide additional information.

Sincerely,

Stephen W. Inglese, Consultant to Respire Medical, LLC
Quality Solutions and Support, LLC
Phone: 561-251-0876 Email: swi@qss-llc.com

Respire Pink Series - Herbst - EF

Special 510(k)
March 1, 2015

Submitter: Respire Medical LLC
18 Bridge St Ste. 4J
Brooklyn, 11201 NY
Phone: 718-643-7326

Contact: Stephen Inglese
Consultant
Quality Solutions and Support, LLC
Phone: 561-251-0876
Email: swi@qss-llc.com

Table of Contents

List of Appendices

1.0 Medical Device User Fee Cover Sheet

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. 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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) RESPIRE MEDICAL HOLDINGS 18 Bridge st Suite 4J Brooklyn NY 11201 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0475	2. CONTACT NAME David Walton 2.1 E-MAIL ADDRESS david@respiremedical.com 2.2 TELEPHONE NUMBER (include Area code) 718-6437326 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD155290

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?

[X] 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.)

[ ] 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.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] 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).

[ ] YES [X] 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, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[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) 27-Feb-2015

Form FDA 3601 (05/13)

2.0 CDRH Premarket Review Submission Cover Sheet

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 PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
March 1, 2015	(b)(4)	NA

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Respire Medical Holding	3008937561		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
NA	718-643-7326		
Street Address	**FAX Number *(including area code)***		
18 Bridge St Suite 4J	NA		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Brooklyn	NY	11201	USA
Contact Name			
David Walton			
Contact Title	**Contact E-mail Address**		
Chief Executive Officer	david@respiremedical.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Quality Solutions and Support, LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
NA	954-830-0051		
Street Address	**FAX Number *(including area code)***		
PO Box 8271	NA		
City	**State / Province**	**ZIP Code**	**Country**
Holland	MI	49422	USA
Contact Name			
Stephen W. Inglese			
Contact Title	**Contact E-mail Address**		
Founder and CEO	swi@qss-llc.com		

FORM FDA 3514 (1/13) Page 1 of 5 Pages

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify):*

  Minor device modification

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LRK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 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	K131138	1	Respire Pink Series - Herbst	1	Respire Medical
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Device, Anti-Snoring

	Trade or Proprietary or Model Name for This Device		Model Number
1	Respire Pink Series – Herbst - EF	1	NA
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	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LHR	21 CFR §872.5570,	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Dental

Indications *(from labeling)*

The Respire Pink Series – Herbst - EF is indicated to treat mild to moderate OSA (Obstruction Sleep Apnea)

FORM FDA 3514 (1/13) Page 3 of 5 Pages

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.			FDA Document Number *(if known)*
SECTION H	**MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**		
☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Respire Medical Holding		Establishment Registration Number: 3008937561	
Division Name *(if applicable)*: NA		Phone Number *(including area code)*: 718-643-7326	
Street Address: 18 Bridge St Suite 4J		FAX Number *(including area code)*: NA	
City: Brooklyn	State / Province: NY	ZIP Code: 11201	Country: USA
Contact Name: David Walton	Contact Title: ?	Contact E-mail Address: david@respiremedical.com	
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ 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	
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ 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 (1/13) Add Continuation Page Page 4 of 5 Pages

SECTION I	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.					
1	Standards No. NA	Standards Organization ISO 10993	Standards Title Biological Evaluation of Medical Devices	Version 1992	Date NA
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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.

FORM FDA 3514 (1/13) Page 5 of 5 Pages

3.0 510(k) Cover Letter

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

uality Solutions and Support, LLC
Quality Success……is the ability to improve with knowledge

Re: Special 510(k) Notification (21 CFR 807.90(e)) for Respire Pink Series – Herbst - EF

Dear Reviewer,

The following Special 510(k) is submitted in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Respire Medical, LLC proposes to introduce into interstate commerce, for commercial distribution the Pink Series – Herbst - EF.

This submission contains methods, data and analysis of these data which the Sponsor considers “Trade Secret”, commercially privileged and confidential. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act. In accordance with 21 CFR §807.95; the submitter considers their intent to market the device to be confidential commercial information.

The Respire Pink Series – Herbst was previously cleared in K131138. The only modification to the device since its previous clearance is that the end - user now has an option to select a chrome (Wironit material) along with the original Acrylic material used to create the device plates. This modification represent a minor device modification and do not affect the indications for use and are therefore appropriate for a Special 510(k).

Class II Special Controls Guidance Document: Intraoral Devices for Snoring and / or Obstructive Sleep Apnea; Guidance for Industry and FDA was reviewed.

An eCopy is provided with this submission and is an exact duplicate of the original paper submission.

The following submission details are provided in accordance with FDA Guidance documents

Device Common Name: Device, Anti-Snoring

Device Proprietary Name: Respire Pink Series – Herbst - EF

Submitter: Respire Medical, LLC
18 Bridge St Ste 4J
Brooklyn, NY 10021
Phone: 718-643-7326

Contact: Stephen Inglese
Consultant
Quality Solutions and Support, LLC
Phone: 561-251-0876
Email: swi@qss-llc.com

Classification Regulation: 21 CFR §872.5570, Class II – Device Anti-Snoring
Panel: Dental
Product Code: LRK

Design and Use of Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?[A]		X
Does the device contain components derived from a tissue or other 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
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Please do not hesitate to contact me at any time during the review process to answer questions or provide additional information.

Sincerely,

Stephen W. Inglese, Consultant to Respire Medical, LLC
Quality Solutions and Support, LLC
Phone: 561-251-0876 Email: swi@qss-llc.com

4.0 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
NA

Device Name
Respire Pink Series - Herbst - EF

Indications for Use *(Describe)*
The Respire Pink Series - Herbst - EF is indicated to treat mild to moderate OSA.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Respire Pink Series – Herbst – EF is provided below:

Device Common Name: Device, Anti-Snoring

Device Proprietary Name: Respire Pink Series – Herbst - EF

Submitter: Respire Medical, LLC
18 Bridge St Ste 4J
Brooklyn, NY 10021
Phone: 718-643-7326

Contact: Stephen Inglese
Consultant
Quality Solutions and Support, LLC
Phone: 561-251-0876
Email: swi@qss-llc.com

Date Prepared: .March 1st 2015

Classification Regulation: 21 CFR §872.5570, Class II – Device Anti-Snoring

Panel: Dental

Product Code: LRK

Predicate Device: K131138 – Submitter's own previously cleared device

Indication for Use: The Respire Pink Series – Herbst - EF is indicated to treat mild to moderate OSA (Obstruction Sleep Apnea)

Device Description:
The Respire Pink Series – Herbst - EF (Endurance Frameworks) – is available with a hard device fitting surface. The hard surface consists of Acrylic (side plates) and chrome - Wironit material (upper / Palatal and lower / Lingual plates). **Refer to Figure 1 Representative Drawing**. The device is retained with ball and clasps which allows the device to be tightened if it becomes loose. The device is a mandibular advancement splint that holds the jaw in a forward position to help keep the tongue and supporting tissues in a

position to help maintain an open airway, which helps in the treatment of snoring and mild to moderate obstructive sleep apnea

The Herbst hardware on the side of the device allows the patient to move forward and left and right, but not backwards. These movements give the patient some freedom to move which is important for their comfort and overall success of the device. The upper and lower components are connected by an adjustable hinge, thus patient can open and close while wearing the appliances.

Figure 1 – Respire Pink Series – Herbst – EF – Front View

Performance Data:
The subject of this 510(k) is a modification to the material used for the manufacturing of the top and bottom trays of the device. The material "Wironit" is a safe widely used dental material and demonstrated via biocompatibility and cytotoxicity testing demonstrated within this submission. See Appendix 4. Based on the completed risk analysis which determined the added material showed the risks were mitigated to acceptable levels in addition to the testing accomplished, the device performance is similar to that of the originally cleared predicate device.

Substantial Equivalence:
The modification of the added material to the originally cleared device is demonstrated in Chart 1. The device function remains the same, the option for the Wironit material for the upper and lower tray provides the patient with a more comfortable fit and durability . Therefore the modified device is substantially equivalent to the previously cleared Respire Pink Series – Herbst.

Chart 1

Substantial Equivalence Topic	Respire Pink Series – Herbst	Respire Pink Series – Herbst - EF
510(k)	K131138	NA
Company Name	Respire Medical	Respire Medical
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)
Device Name	Device, Anti Snoring	Device, Anti Snoring
Product Code	LRK	LRK
Classification	Class II	Class II
Intended Use	The Respire Pink Series - Herbst is indicated to treat mild to moderate OSA.	The Respire Pink Series - Herbst – EF is indicated to treat mild to moderate OSA.
Single or Multiple Use	Multiple Use	Multiple Use
Target Population	Adult Patients	Adult Patients
Prescription or OTC Use	Prescription	Prescription
Device Components	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp
Appliance Design	Customized device Rigid tray two pieces Upper/Lower acrylic.	Customized device Rigid tray / two pieces / Upper and Lower / Acrylic and Wironit
Device Functionality	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep Upper and lower tray unhook for easy removal from

Substantial Equivalence Topic	Respire Pink Series – Herbst	Respire Pink Series – Herbst - EF
	mouth. Works by mandibular advancement. Adjustable using titration keys.	mouth Works by mandibular advancement Adjustable using titration keys
Mandibular Advancement Range	6mm	6mm
Raw Material: Side / Upper and Lower Trays	Acrylic (side and upper and lower trays)	Acrylic (side) and Wironit (upper and lower trays)
Raw Material: Metal Components	Stainless Steel	Stainless Steel
Colorants	Pink	Pink

Note: Bold “Substantial Equivalence Topic” – Difference between the cleared device and the modifications called out in this submission

6.0 Truthful and Accuracy Statement

(As required by 21 CFR §807.87(j))

I certify that, in my capacity as Chief Executive Officer for Respire Medical, LLC, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

3/2/15

Date

7.0 Class III Summary and Certification

Not applicable. This is not a Class III device..

8.0 Declarations of Conformity, Summary Reports and Guidance Documents

Declaration of Conformity

As required for a Special 510(k), the Declaration of Conformity with Design Control statements are provided in Appendix 1

Summary Reports

Standard data reports is provided in Appendix 5

Related Submissions

Other than the original 510(k) clearances referenced in this Special 510(k) (K131138), there are no related submissions (i.e., Pre-Submissions, IDEs, prior NSE decisions, etc.)

Guidance Documents

Class II Special Controls Guidance Document: Intraoral Devices for Snoring and / or Obstructive Sleep Apena; Guidance for Industry and FDA

9.0 Executive Summary

9.1 Device Description

Respire Pink Series – Herbst - EF is a customized device for each patient which consists of two dental plates, upper and lower, made of Acrylic and Wironit..

The Respire Pink Series – Herbst- EF is a mandibular advancement splint that holds the jaw in a forward position to help keep the tongue and supporting tissues in a position to help maintain an open airway, which in turn helps in the treatment of snoring and mild to moderate obstructive sleep apnea.

The Herbst hardware on the side of the devices allow the patient to move forward and left and right, but not backwards. These movements give the patient some freedom to move which is important for their comfort and overall success of the device. The upper and lower components are connected by an adjustable hinge, thus patient can open and close while wearing the appliances.

Respire Pink Series – Herbst - EF has a hard device fitting surface which is constructed of Acrylic and Wironit and retained with ball clasps, this allows the device to be tightened if it becomes loose.

9.2 Indication for Use Statement

The Respire Pink Series – Herbst – EF is indicated to treat mild to moderate OSA.

9.3 Device Modifications

Wironit material is the added material to the device to provide the patient with comfort and durability – Wironit is a classic dental alloy. A leading alloy, known and used world-wide for more than 30 years. Wironit® and Wironit® Extra Hard. Both offer an excellent physical properties and finish. This material can be used on the Respire Pink Series – Herbst – EF upper and lower trays as seen in **Figure 1 Representative Drawing.**

See MSDS sheet in Appendix 4 for Wironit by BEGO Bremer Goldschlaegerei.

9.4 Summary of Design Verification and Validation Activities

In accordance with the design and control procedures, design verification and validation testing of the modified device were performed based on the risk results of the risk analysis. The risk analysis method used was a Product Risk Analysis Worksheet. The results demonstrated within the worksheet with the addition of the Wironit material to the Respire Pink Series – Herbst – EF device and that the analysis showed that after mitigation and characterization of each risk associated with the

added material the risk severity and probability were acceptable. The complete risk analysis detail is provided in Appendix 3.

Testing of the Wironit material was either accomplished prior to the material being acquired or accomplished once the decision to utilize the material was made. All testing documents can be found in Appendix 4. The following tests were accomplished:

- Biocompatibility – Material Manufacturer
- Minimal Essential Medium (MEM) Elution – Respire Medical

The following material safety sheet is provided:

- A MSDS safety sheet for Wironit

Biocompatibility was accomplished according to the standards of ISO 10993 the results of testing determined that the material didn't cause skin irritation or allergenic sensitization.

The Minimal Essential Medium (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. The testing passed with a reactivity of 0 (zero) or none.

9.5 Substantial Equivalence

The modification made to the Respire Pink Series – Herbst – EF is substantially equivalent to the originally cleared Respire Pink Series – Hebrst device. The single modification of providing the patent with a more comfortable and durable fitting device in using Wironit instead of Acrylic for the upper and lower device trays. The modified device remains safe and effective as the original cleared device.

10.0 Device Description

10.1 General Description

The Respire Pink Series – Herbst - EF (Endurance Frameworks) – is available with a hard device fitting surface. The hard surface consists of acrylic (side plates) and chrome - Wironit material (upper and lower plates). **Refer to Figure 2 Representative Drawing**

The device is retained with ball and clasps which allows the device to be tightened if it becomes loose.

The device is a mandibular advancement splint that holds the jaw in a forward position to help keep the tongue and supporting tissues in a position to help maintain an open airway, which helps in the treatment of snoring and mild to moderate obstructive sleep apnea

The Herbst hardware on the side of the devices allow the patient to move forward and left and right, but not backwards. These movements give the patient some freedom to move which is important for their comfort and overall success of the device. The upper and lower components are connected by an adjustable hinge, thus patient can open and close while wearing the appliances.

10.2 Principles of Design

(b)(4) [redacted].

10.3 Material Finish –

(b)(4) [redacted]

Figure 2 – Acrylic (Sides) and Wironit - Chrome Finish (Top and Bottom) – Front View

10.4 Device Modifications

Added Material –

Wironit – Wironit is a classic dental alloy. A leading alloy, known and used world-wide for more than 30 years. Wironit® and Wironit® Extra Hard is extremely easy to cast..

See MSDS sheet in Appendix 4 for Wironit by BEGO Bremer Goldschlaegerei.

11.0 Substantial Equivalence Discussion

11.1 Technological Comparison

The Respire Pink Series – Herbst – EF device that is the subject of this 510(k) is substantially equivalent to the previously cleared version of Respire Pink Series – Herbst in K131138. The only modification to the device is the material the patent now has the option to use. The upper and lower trays which can be made of Acrylic (cleared under K131138) can now be made of Wironit. **Chart 2** demonstrates the comparison between the previously cleared device and the modification for the device identified in this submission.

Chart 2

Substantial Equivalence Topic	Respire Pink Series – Herbst	Respire Pink Series – Herbst - EF
510(k)	K131138	NA
Company Name	Respire Medical	Respire Medical
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)
Device Name	Device, Anti Snoring	Device, Anti Snoring
Product Code	LRK	LRK
Classification	Class II	Class II
Intended Use	The Respire Pink Series - Herbst is indicated to treat mild to moderate OSA.	The Respire Pink Series - Herbst – EF is indicated to treat mild to moderate OSA.
Single or Multiple Use	Multiple Use	Multiple Use
Target Population	Adult Patients	Adult Patients
Prescription or OTC Use	Prescription	Prescription
Device Components	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp
Appliance Design	Customized device Rigid tray two pieces Upper/Lower	Customized device Rigid tray / two pieces / Upper and

Substantial Equivalence Topic	Respire Pink Series – Herbst	Respire Pink Series – Herbst - EF
	acrylic.	Lower / Acrylic and Wironit
Device Functionality	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep Upper and lower tray unhook for easy removal from mouth Works by mandibular advancement Adjustable using titration keys
Mandibular Advancement Range	6mm	6mm
Raw Material: Side / Upper and Lower Trays	Acrylic (side and upper and lower trays)	Acrylic (side) and Wironit (upper and lower trays)
Raw Material: Metal Components	Stainless Steel	Stainless Steel
Colorants	Pink	Pink

Note: Bold "Substantial Equivalence Topic" – Difference between the cleared device and the modifications called out in this submission

Design Material Substantial Equivalence

Figure 3 demonstrates the originally cleared device of full Acrylic material that is both the sides and upper and lower trays are made of Acrylic. This figure shows the Herbst hardware, ball, and clasp on the sides.

Figure 3

Figure 4 demonstrates the modified device. The sides remain Acrylic as in the orginal cleared submission but the upper and lower trays are replaced with Wironit. This figure demonstrates the Herbst hardware and ball and clasp on the sides.

Figure 4

11.2 Substantial Equivalence Conclusion

The modification of the Respire Pink Series – Herbst to Respire Pink Series – Herbst – EF as demonstrated in the above chart is to only provide the patent with an option to have the upper and lower trays utilize the Wironit material instead of Acrylic. This provides the patient with a more comfortable fitting device. The modified device is substantially equivalent to previously cleared Respire Pink Series – Herbst device. The device remains both safe and effective as originally cleared.

12.0 Proposed Labeling

The intended use of the modified device as described in the labeling has not changed as a result of the modifications.

The proposed labeling is demonstrated in Appendix 2 of both the Doctor / Patient Oral Appliance Care and Instruction and packaging label.

Both the Doctor / Patient Appliance Care and Instruction and packaging label are highlighted to demonstrated the “Respire Pink Series – Herbst – EF” device.

13.0 Performance Testing – Bench

To demonstrate the safety and effectiveness of the new device material, Wironit material was tested in two (2) different studies… See Appendix 4 for the testing completed details.

13.1 MSDS – Sheet

A MSDS safety sheet for Wironit contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the material.

13.2 Biocompatibility Material – Manufacturer

Biocompatibility was accomplished according to the standards of ISO 10993 the results of testing determined that the material didn't cause skin irritation or allergenic sensitization.

13.3 Minimal Essential Medium (MEM) Elution – Respire Medical

The Minimal Essential Medium (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. The testing passed with a reactivity of 0 (zero) or none.

Declaration of Conformity with Design Controls

Verification Activities

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

David Walton

Chief Executive Officer

Respire Medical, LLC

(Signature)

2/20/15

(Date)

Declaration of Conformity with Design Controls

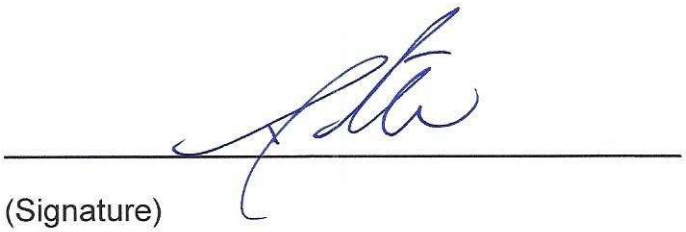
Manufacturing Facility

The manufacturing facility, Respire Medical, LLC is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

David Walton

Chief Executive Officer

Respire Medical, LLC



(Signature)

3/2/15

(Date)

Patient Instructions

Do not bite down into place. This may cause clasping or soft layer distortion

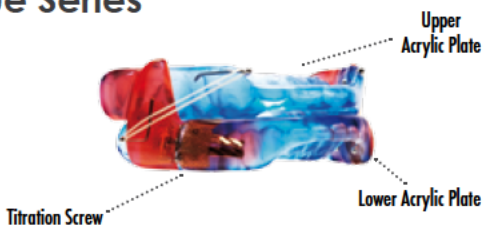
Understanding Sleep Apnea

Sleep Apnea is the temporary stoppage of breathing during sleep, often resulting in daytime sleepiness. There are three (3) types of sleep apnea; Obstructive. Central and Mixed; of the three, obstructive is the most common. Despite the difference in the root cause of each, people with undiagnosed sleep apnea stop breathing repeatedly during their sleep. sometimes hundreds of times during the night, and as often as long as a minute. Obstructive Sleep Apnea (OSA) is caused by a blockage in the airway, usually when soft tissue in the rear of the throat collapses and closes during sleep. In Central Sleep Apnea. the airway is not blocked but the brain tails to signal muscles to breathe. Mixed Apnea, as the name implies, is a combination of the two. With each apneic event. the brain briefly arouses people with sleep apnea in order for them to resume breathing. Consequently, sleep is extremely fragmented and of poor quality. Respire Medical Oral Appliances are designed to position the jaw in a way to maintain an open airway, allowing for the patient to inhale and exhale more air per breath.

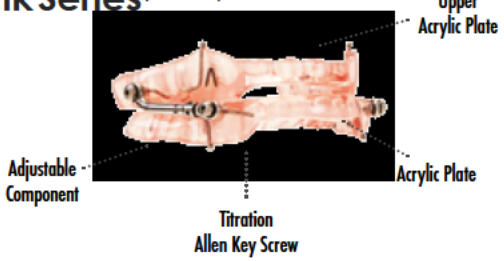
The following is for the:

Use and care of respire medical oral appliances

Blue Series



Pink Series (Herbst)



Blue Series EF

Pink Series EF

1. Place upper component gently onto upper teeth by hand. Press up to ensure plate is seated securely and fits comfortably.

2. Place lower component gently by hand onto lower teeth. Press down on both sides to ensure plate is seated securely and fits comfortably.

3. Once the upper and lower components are seated firmly in mouth, make sure the appliances flat panels are in even contact throughout the ark when Jaw is closed.

4. If appliance needs adjustment, contact your clinician for guidance and recommendation.

Ongoing Maintenance

1. Brush teeth thoroughly. Failure to brush and floss can lead to premature discoloration of appliance. Discoloration does not affect function or longevity of the appliance.

2. Clean appliance daily. Using soap and water.

3. Upon removal from the mouth, a plan should be rinsed and cold water and then clean with soap and a soft brush.

4. The appliance should be soaked and partial denture cleaner (recommendation, tablet of Polident) for five (5) minutes once a week.

SPECIAL NOTE- It may take a few nights to get used to the appliance. Some muscle tenderness may occur. Adjusting any screw a respire medical or appliances should be performed by a doctor at patient follow-up visit. your clinician will discuss adjustments and follow up appointments with you.

WARNING: IF ANY SEVERE PAIN OCCURS, PLEASE CONTACT YOUR PRACTITIONER IMMEDIATELY.

Respire Medical
BREATHE EASY AGAIN

DOCTOR/PATIENT

Oral Appliance

Care & Instructions

718-64-DREAM

18 Bridge Street • Unit 4j • Brooklyn, NY 11201

Phone: 718-643-7326 • Fax: 718-643-7322

www.respiremedical.com • info@respiremedical.com

Doctor Instructions

RESPIRE MEDICAL ORAL APPLIANCE DESCRIPTION

Each device is custom-made. Each device consists of two (2) acrylic dental plates (upper and lower). The attachments on the appliances enable advancement of the appliance.

INDICATION FOR USE

Respire Medical Oral Appliance's are indicated for the treatment of Mild to Moderate Snoring and Obstructive Sleep Apnea(OSA). Our devices are not indicated for treatment of Central Sleep Apnea. Oral sleep appliances are intended to be worm during the night to help place the patient's jaw in an optimal position so they can inhale/exhale more air per breath, thus reducing the patient's snoring and sleep apnea.

CONTRAINDICATIONS

Appliance is contraindicated for patients who:

- Have Central Sleep Apnea
- Have severe respiratory disorders
- Have advanced periodontal disease
- Under 18 years of age
- Allergic to Acrylic (Methyl Methacrylate)
- Allergic to Chrome (Wironit) - Endurance Framework Only

PRECAUTIONS

Dentists should consider the medical history of the patient, including history of asthma, breathing or respiratory disorders, or other relevant health problems. Please refer the patient to the appropriate healthcare provider before prescribing the oral appliance. During the first few weeks some of the following discomforts may be experienced, but will dissipate after consistent usage: Slight tooth discomfort, jaw muscle pain and excessive salivation.

WARNING

Respire Medical recommends the patient have a check-up after 10-14 days of using the device, and every 6 months to ensure a proper fit of the appliance. If any of the conditions listed below occur, stop using the appliance and contact your doctor. Use of the appliance may cause:

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

PRESCRIBING THE ORAL APPLIANCE

CAUTION: Federal law restricts this device to sale by or on the order of a physician/practitioner licensed by the State law in which he/she practices to use or order the use of the device.

SPECIAL NOTE (Herbst Only): The attachment screws of any Respire Medical Oral Appliance are be tightened at each patient follow-up visit to avoid the screw becoming loose.

LIMITED WARRANTY

Respire Medical Oral Appliance Series are unique patented oral appliances which are made with high quality materials. If your Respire Medical oral appliance is broken, stop using the appliance. Contact your physician for repair - immediately. Our appliances are warrantied for one year from the date of delivery. This warranty is for materials and workmanship. It does not cover loss, misuse or damage while outside its normal use.

Package contents - Please be sure to check package contents. Each oral appliance comes with the necessary tools for ease of insertion.

1. Snoring / Sleep Apnea Device
2. Protective Case
3. Bite Registration Plate And Tray
4. Upper and Lower Patient Molds
5. Titration Screw Key
6. Allen Key (Herbst)

Blue Series

INSERTION

It is recommended to insert the upper component first then the lower. To remove, take out the lower component then the upper. Some devices may have different paths of insertion, so some may be best inserted anterior first (left side) then posterior (right side).

TITRATION

To titrate the screw, place screw driver at the bottom of the arrow. Turn in the direction of the arrow. One (1/4) turn is equal to 0.2 millimeter.

Adjustment (mm)	0.2	0.4	0.6	0.8	1.0	1.2	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.0	3.2	3.4	3.6	3.8	4.0	4.2	4.4	4.6	4.8	5.0	5.2	5.4	5.6	5.8	6.0
Turns (90 degree)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30

Blue Series Endurance Framework

Two (2) Types of Respite Blue Series

1. Hard/Soft Device - Dual laminate layer that provides a soft layer on the tooth surface. ***Note:*** *If device needs trimming, please use heat resistant bur (green strip) or blue rubber cone.*

2. Hard Device - All acrylic and retained with ball clasps; allows device to be tightened if it becomes loose. ***Note:*** *If device needs trimming - regular acrylic burs work fine.*

The EF's all chrome anterior allows for additional lingual space and durability.

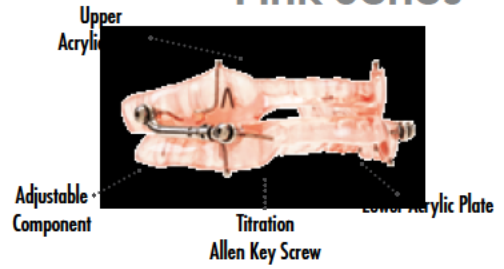
Pink Series Herbst

INSERTION

It is recommended that you hold the upper and lower components together. Place the upper component over the teeth, have patient press over the lower teeth. Do not bite into place. Some devices may have different paths of insertion, so some may be best inserted anterior first (left side) then posterior (right side).

TITRATION

To tirtrate the device, place wrench into hole. Turn in the direction of the plus (+) sign. One (1) turn is equal to .0625 mm. Sixteen (16) turns is equal to 1 mm. Maximum Protrusion is 6 mm = 96 Turns (90 degrees).



Adjustment (mm)	0.0625	0.25	0,5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0
Turns (90 degree)	1	4	8	16	24	32	40	48	56	64	72	80	88	96

Two (2) Types of Pink Series - HERBST

1. Hard/Soft Device - Dual laminate layer that provides a soft layer on the tooth surface. ***Note:*** *If device needs trimming, please use heat resistant bur (green strip) or blue rubber wheel bur.*

2. Hard Device - All acrylic and retained with ball clasps; allows device to be tightened if it becomes loose. ***Note:*** *If device needs trimming - regular acrylic burs work fine.*

Pink Series Endurance Framework

The EF's all chrome anterior allows for additional lingual space and durability.

Device identification label

Respire Medical

RESPIRE PINK SERIES - HERBST - E F

Snoring device Rx only

Attention, See instruction for Use Lot no#99999 Catalog No#

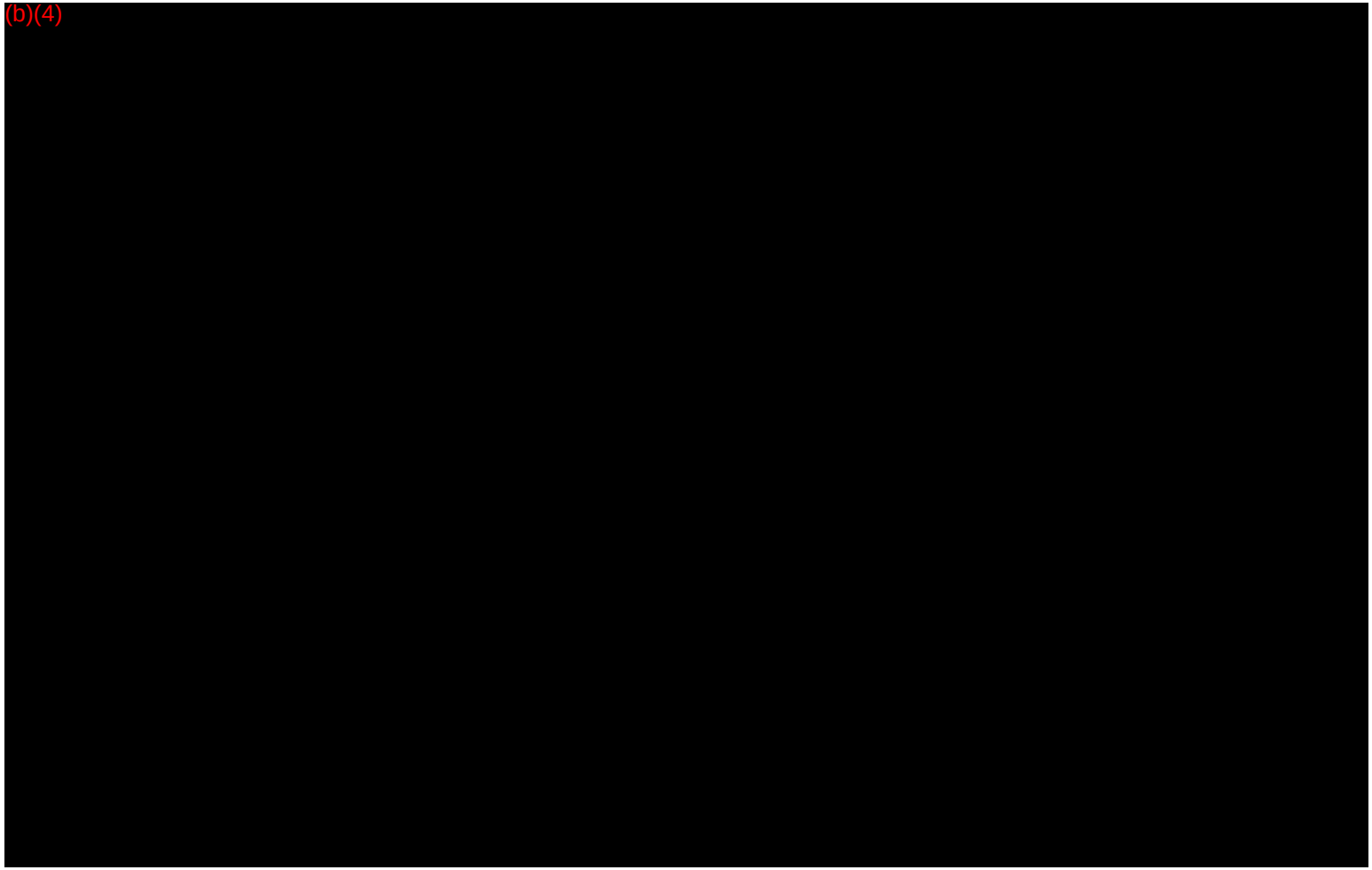
Outer Packaging label

Caution: Federal law restricts this device to sale by or on the order of a physician / practitioner licensed by the law of the State in which he practices to use or order the use of the device.

Manufactured **by** Respire Medical LLC
18 Bridge St., Brooklyn, NY 11201.
(T) 718-643-7326, (F) 718-643-7322, www.RespireMedical.com
Made in China

Confidential

(b)(4)



(b)(4)

(b)(4)

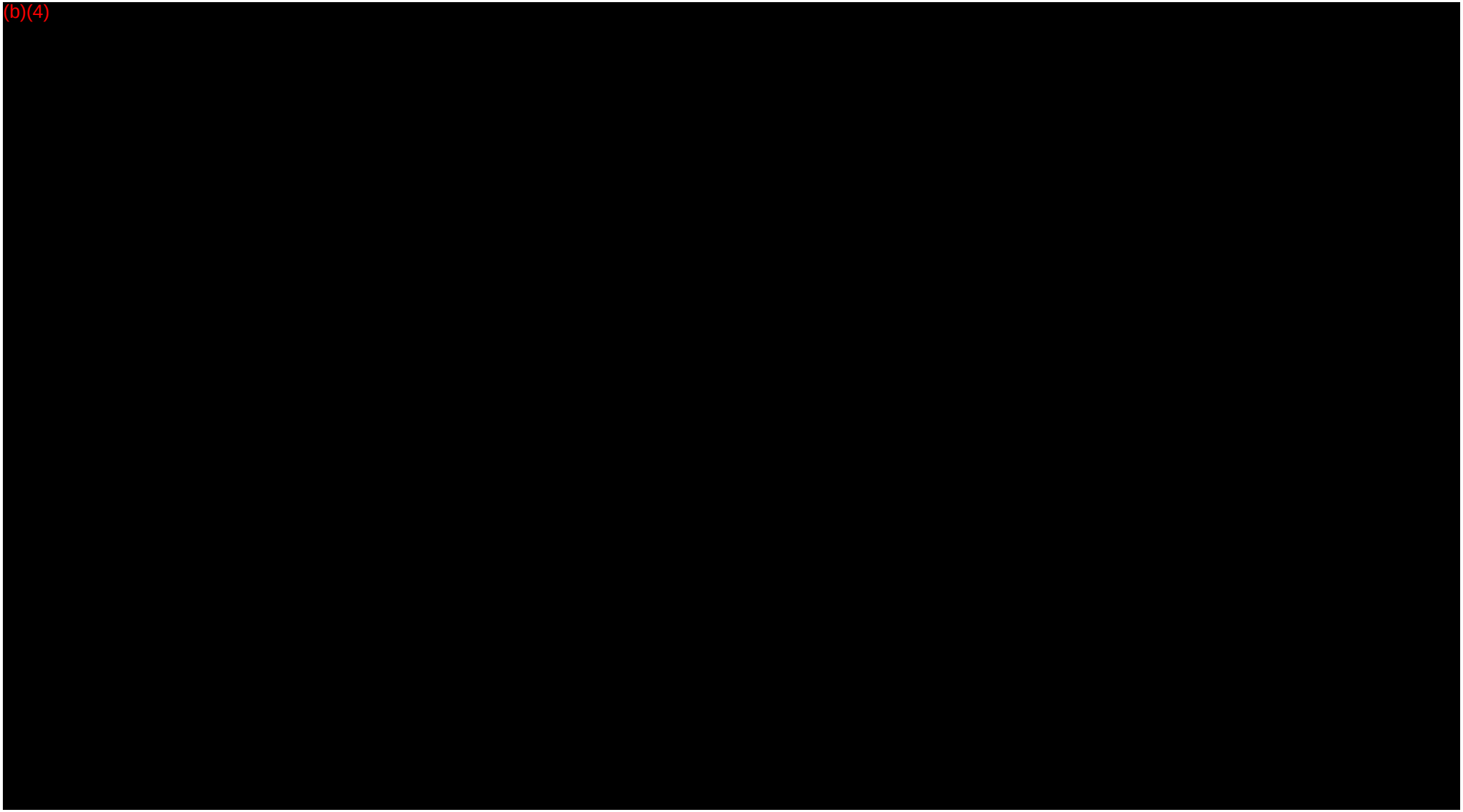
(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



(b)(4)

(b)(4)

(b)(4)

(b)(4)

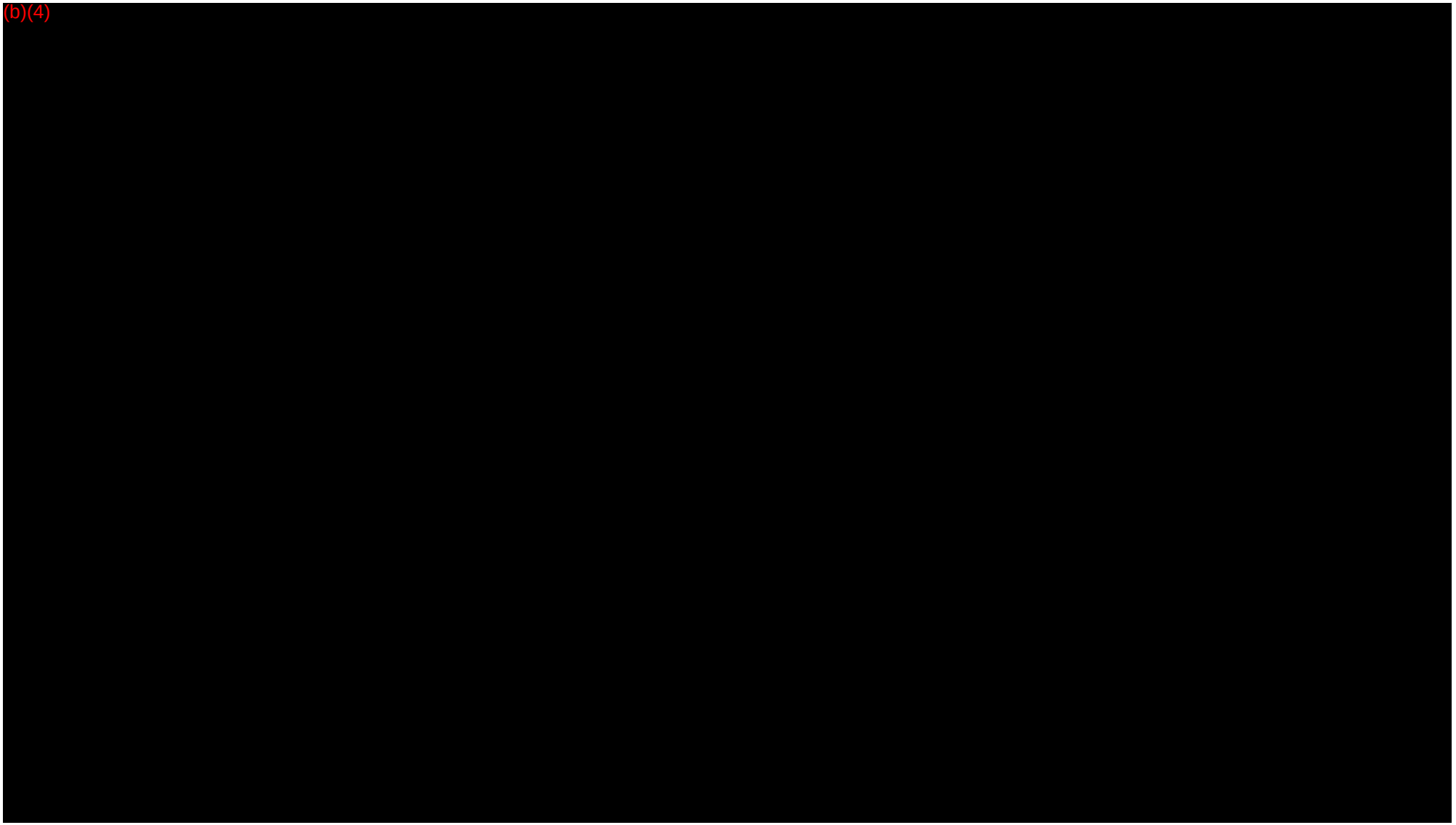
(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



(b)(4)

(b)(4)

(b)(4)

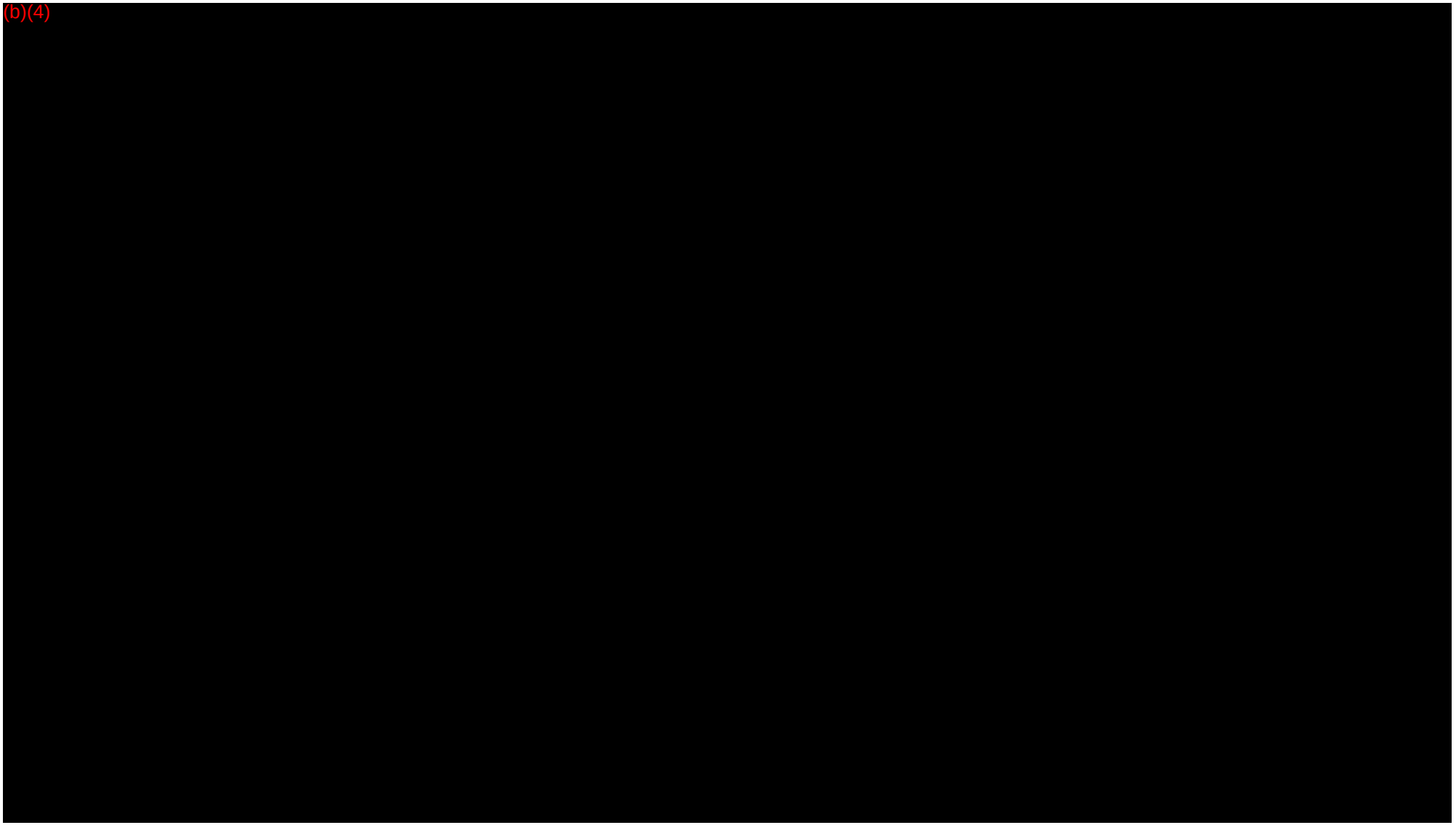
(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



(b)(4)

Material Safety Data Sheet

(b)(4)

(b)(4)

(b)(4)

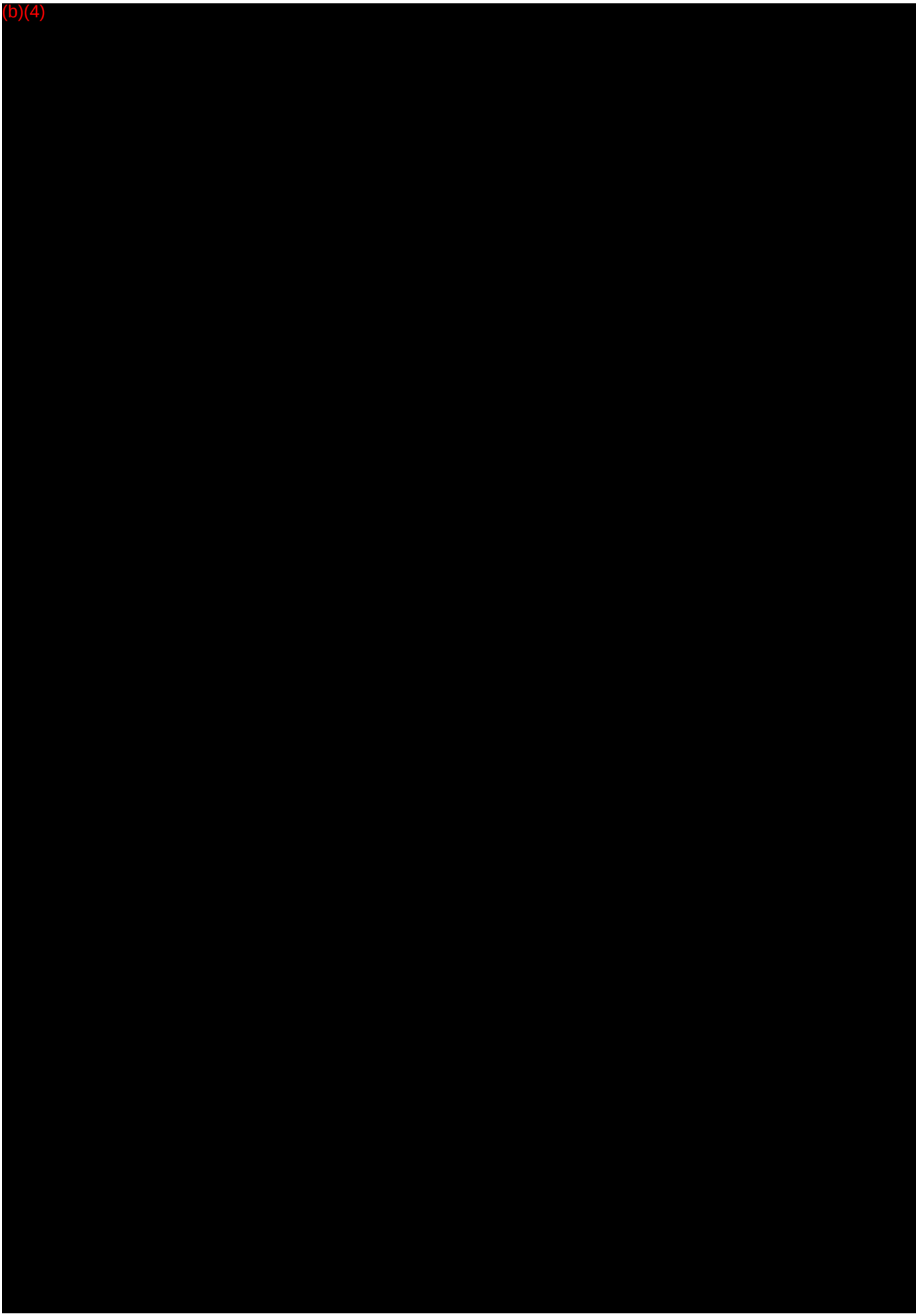
(b)(4)

[redacted]

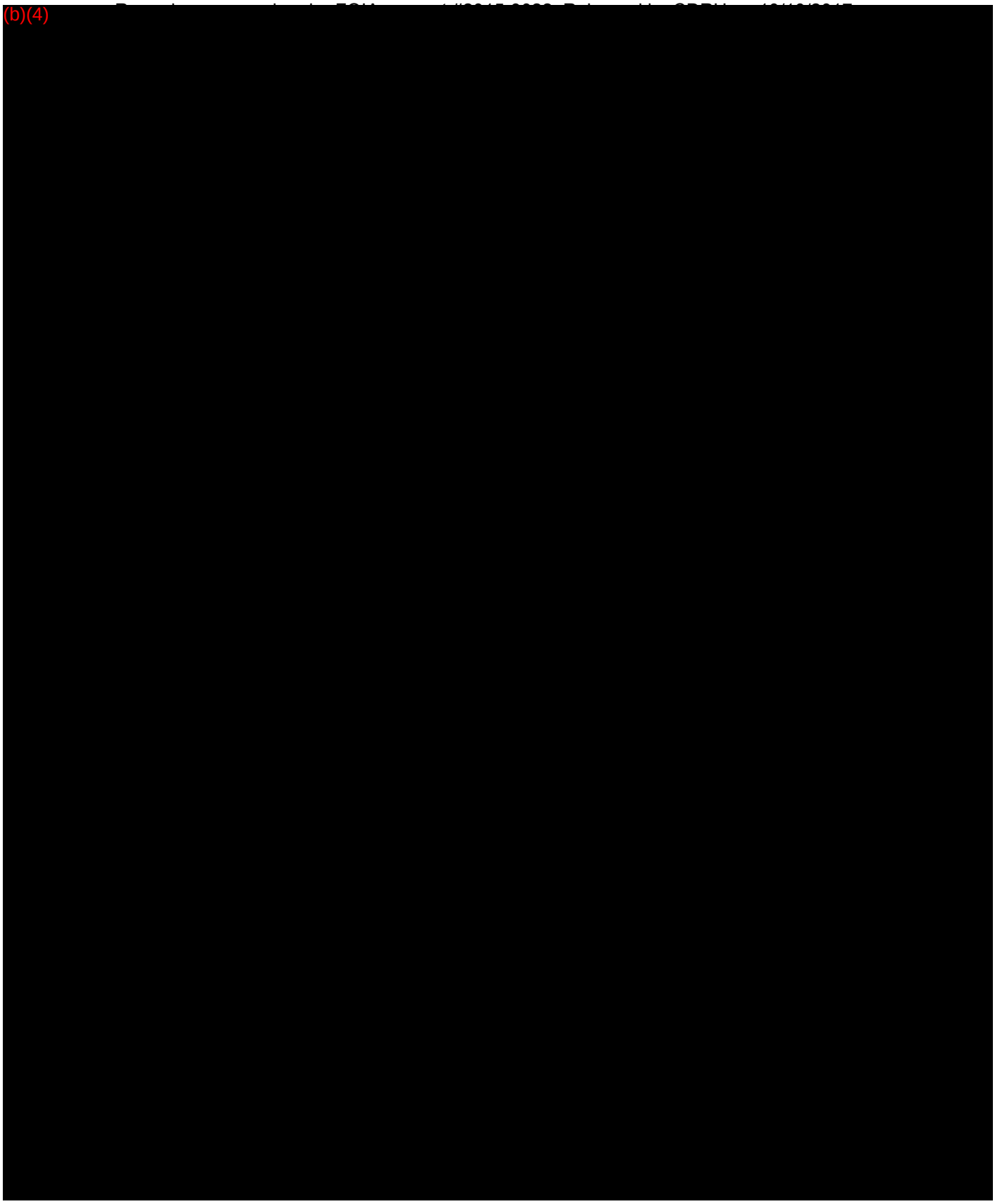
(b)(4)

[redacted]

(b)(4)



(b)(4)



(b)(4) [redacted]

Certificate

Biocompatibility Test

(b)(4) [redacted]

(b)(4) Test Data

(b)(4) Test Data

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

10993 - 1992 Biological Evaluation of Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#NA	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
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]?	☐	☐
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.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
10993 - 1992 Biological Evaluation of Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10993	Biological Evaluation of Medical Devices	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* 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.

❖ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K150572/S1

uality Solutions and Support, LLC
Quality Success.....is the ability to improve with knowledge

July 27, 2015

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

Re: K150572 – Respire Pink Series – Herbst - EF
Additional Information to the 510(k) in response to FDA email: May 5, 2015

Dear Anike Freeman:

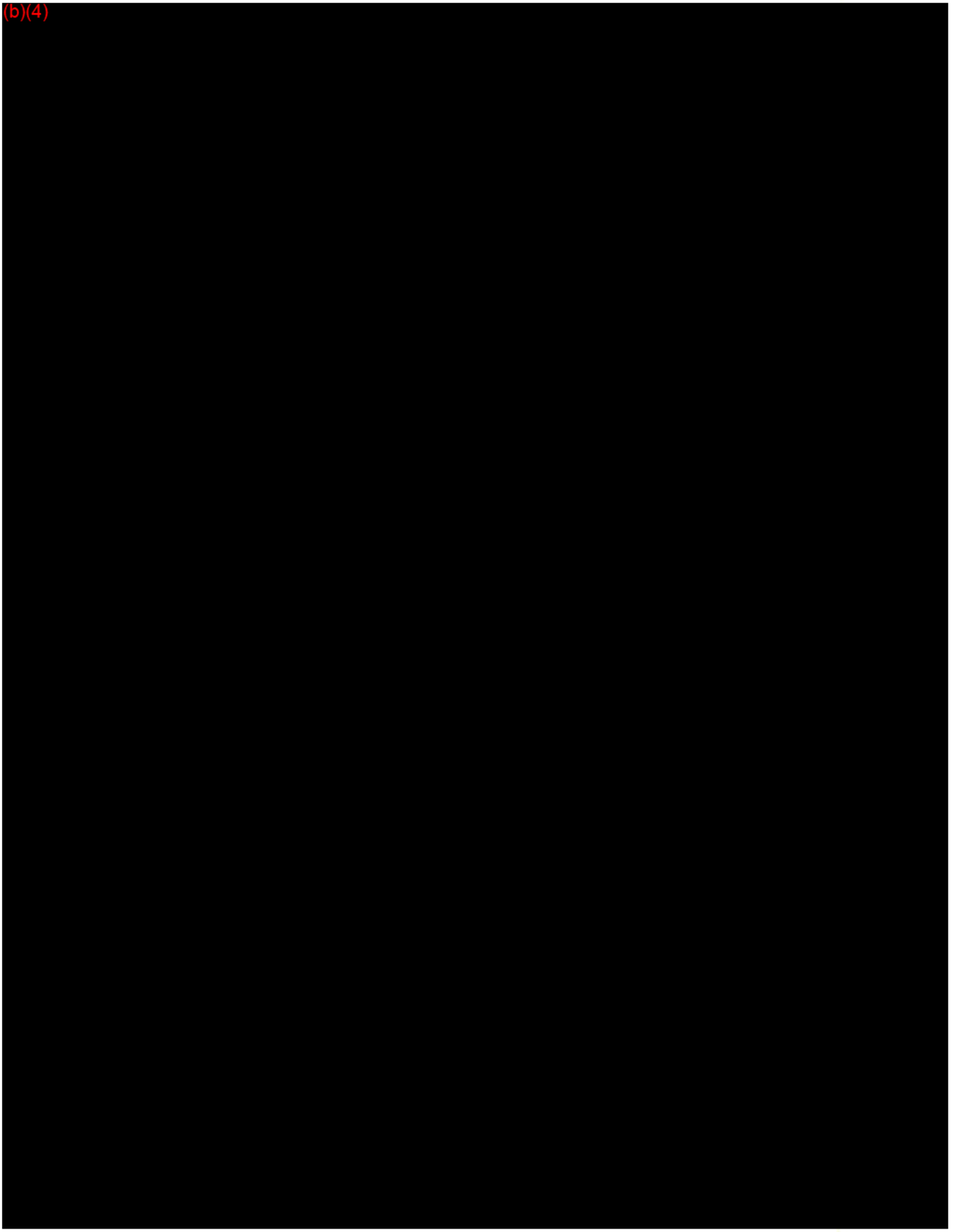
The agency requested information regarding Respire Medical, LLC. 510(k) submission of the Respire Pink Series – Herbst - EF (K150572). Below are the questions asked (in italics) and Respire Medical, LLC. responses (in blue) with the appropriate attachments.

(b)(4)

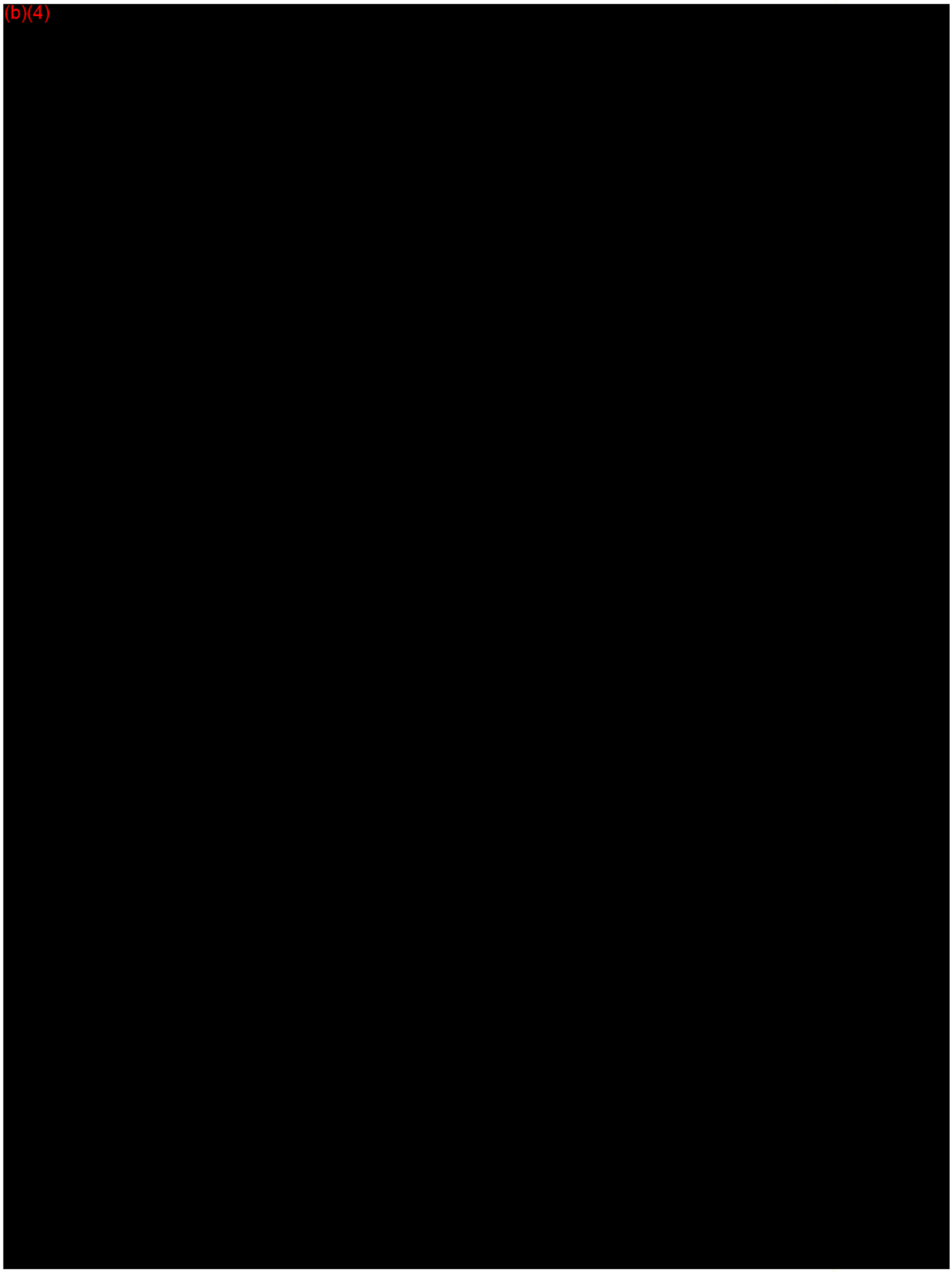
[redacted]

87

(b)(4)



(b)(4)



(b)(4)

If you require any further information, please contact me at 561.251.0876

Sincerely,

Stephen W Inglese (Contact for Submitter)
Founder / CEO
Quality Solutions and Support, LLC
Florida – USA
US Agent
TSgt – USAF Retired
C-561-251-0876
Email – swi@qss-llc.com

Submitter: Respire Medical LLC
18 Bridge St Ste. 4J
Brooklyn, NY 11201
Phone: 718-643-7326

uality Solutions and Support, LLC
Quality Success……is the ability to improve with knowledge

July 27, 2015

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

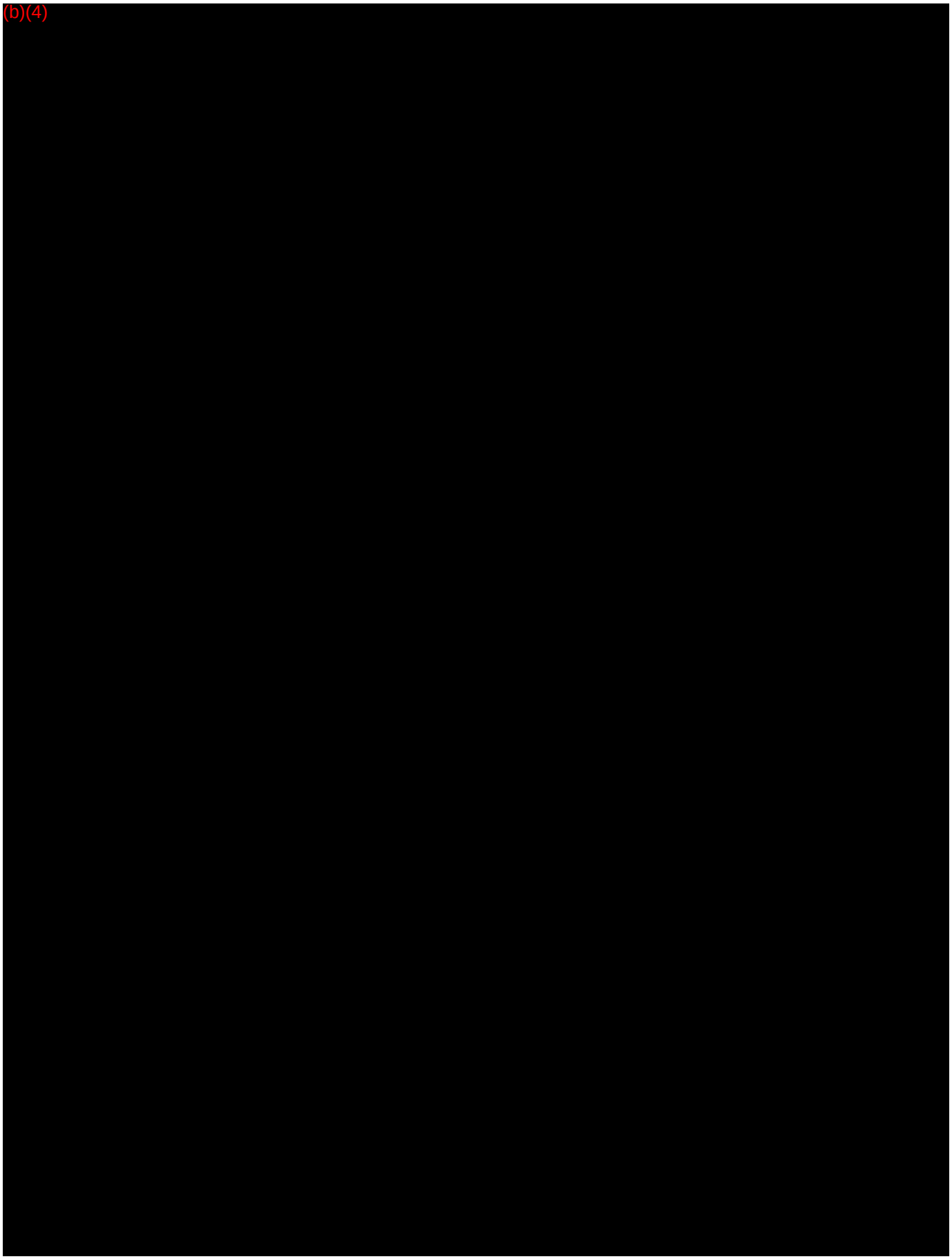
Re: K150572 – Respire Pink Series – Herbst - EF
Additional Information to the 510(k) in response to FDA email: May 5, 2015

Dear Anike Freeman:

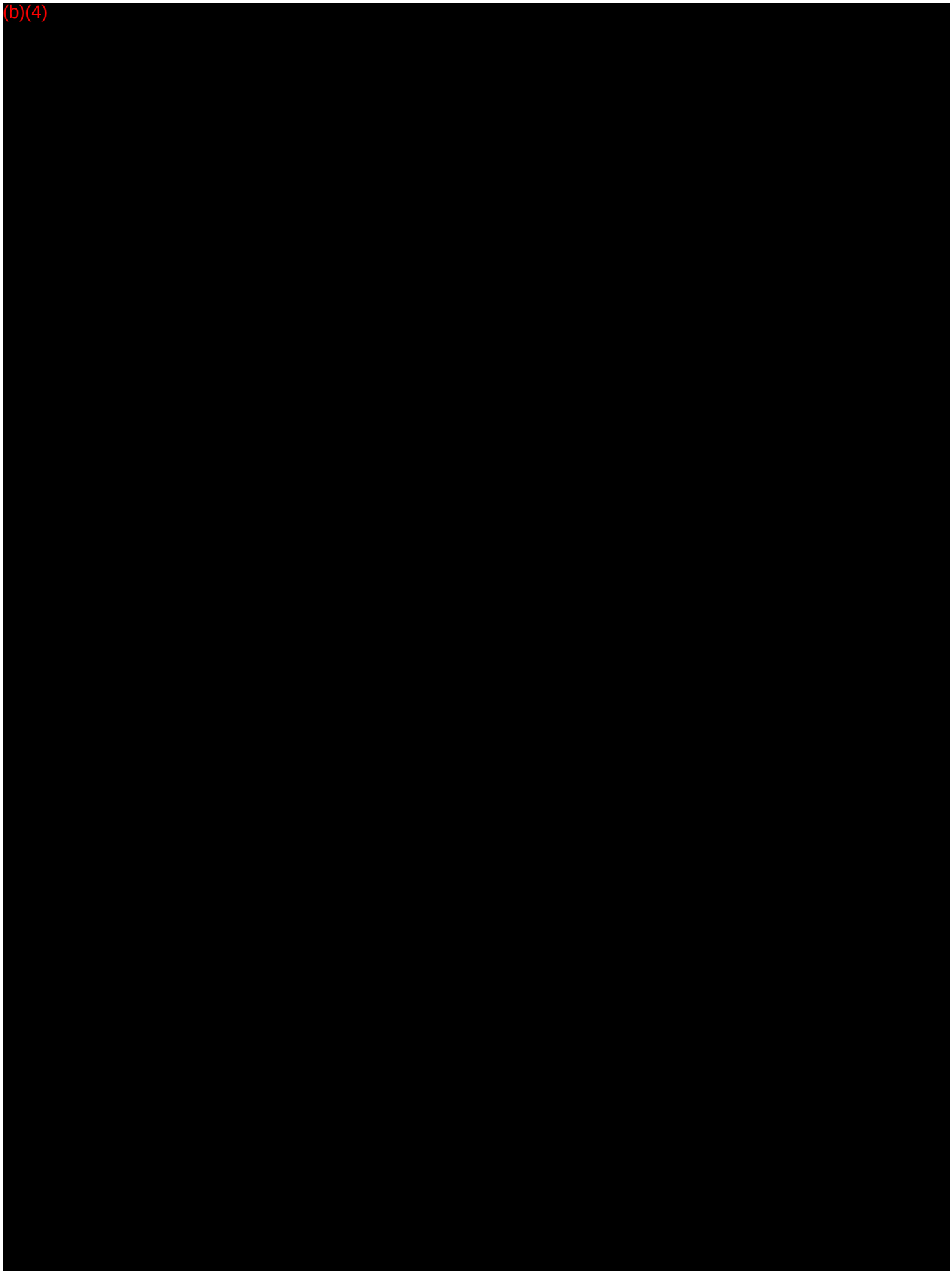
The agency requested information regarding Respire Medical, LLC. 510(k) submission of the Respire Pink Series – Herbst - EF (K150572). Below are the questions asked (in italics) and Respire Medical, LLC. responses (in blue) with the appropriate attachments.

(b)(4)

(b)(4)



(b)(4)



(b)(4)

If you require any further information, please contact me at 561.251.0876

Sincerely,

Stephen W Inglese (Contact for Submitter)
Founder / CEO
Quality Solutions and Support, LLC
Florida – USA
US Agent
TSgt – USAF Retired
C-561-251-0876
Email – swi@qss-llc.com

Submitter: Respire Medical LLC
18 Bridge St Ste. 4J
Brooklyn, NY 11201
Phone: 718-643-7326

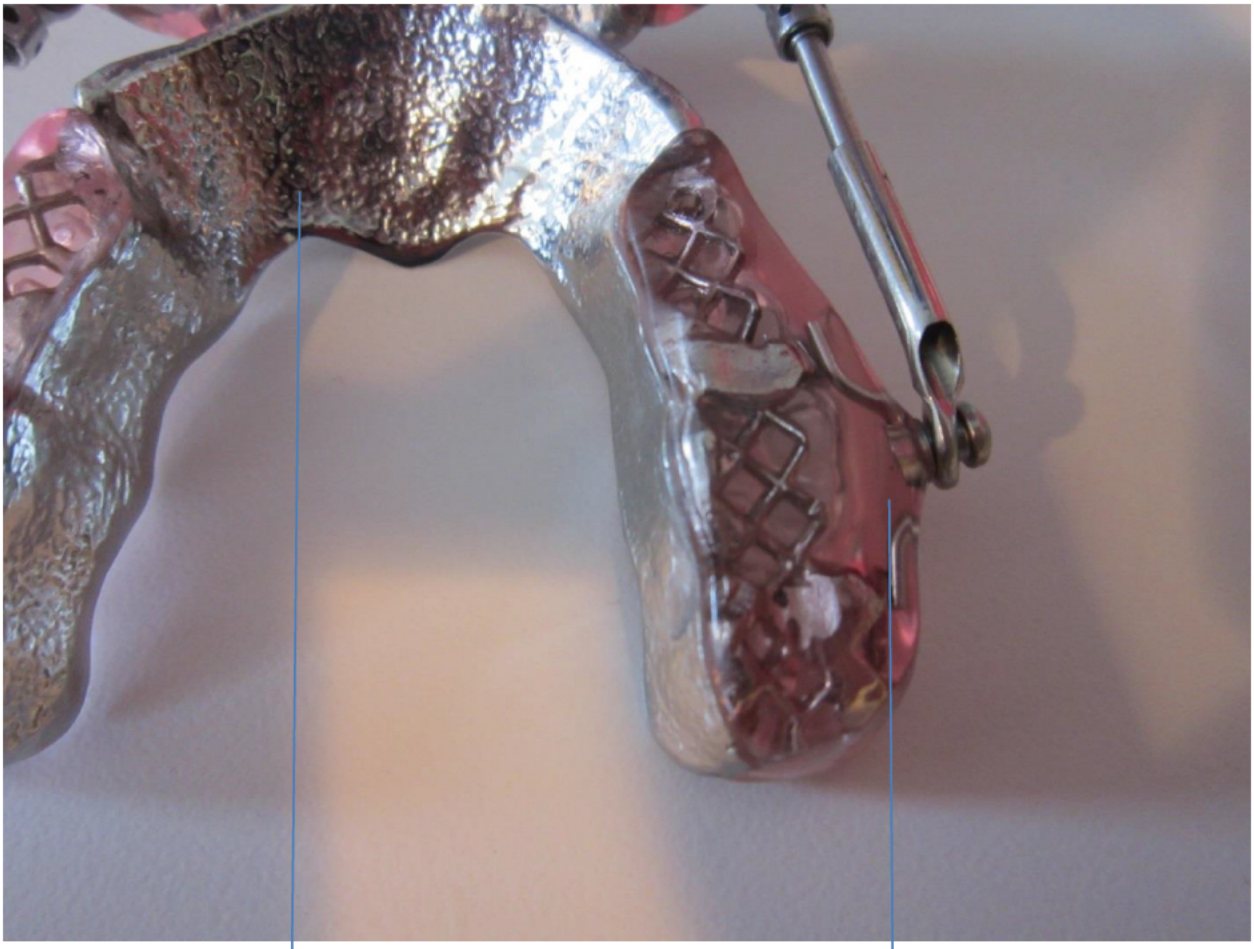


Figure 1 -

This image shows the Wironit mesh creates a mechanical bond to the Acrylic.

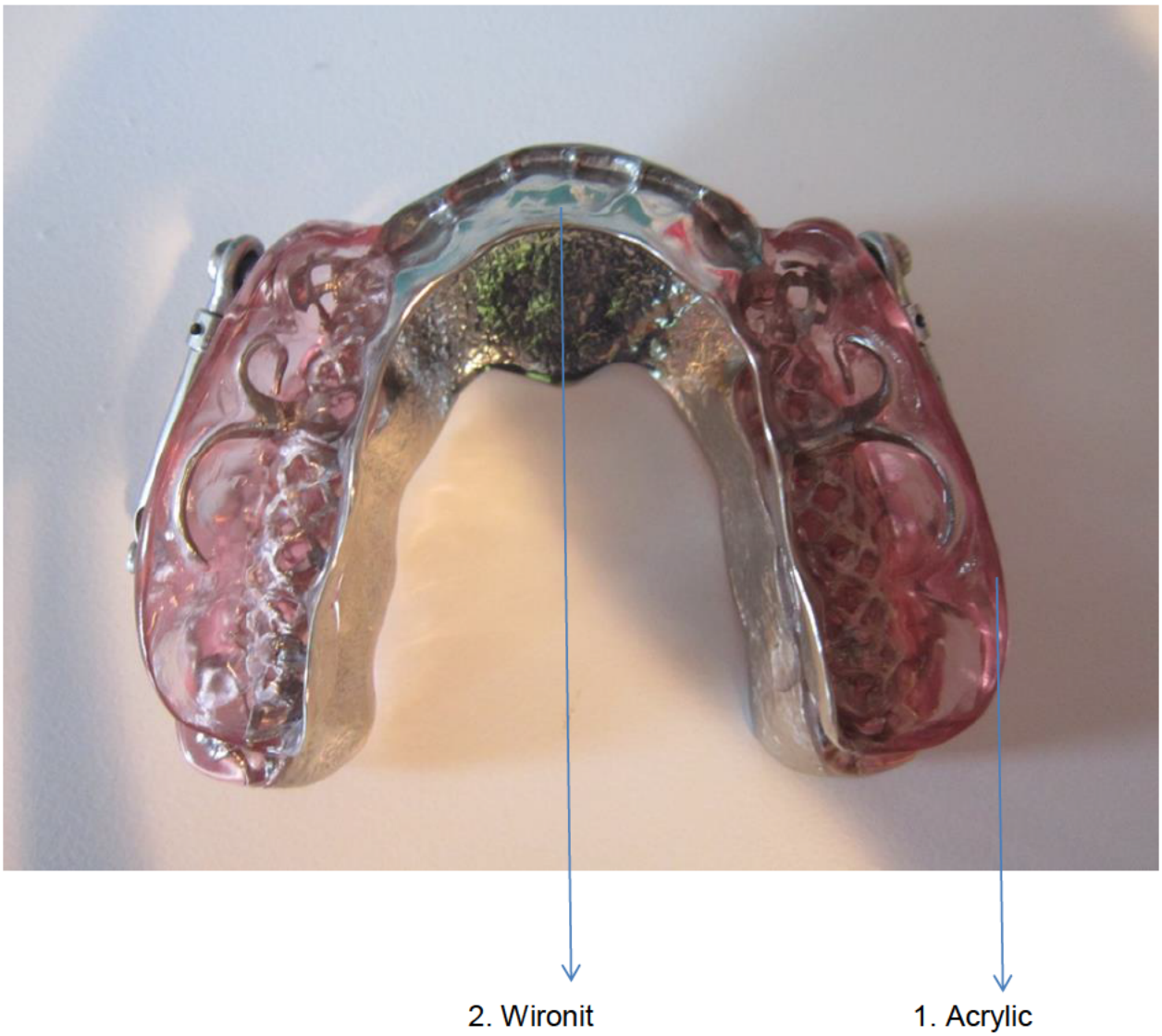


Figure 2 –

This image provides a complete view in how the two (2) materials are joined.

Respire Pink Series – Herbst – EF

Testing Protocol – Material Integrity

Doc: (b)(4)

Rev: 1

Respire Medical
BREATHE EASY AGAIN

(b)(4)

[redacted]

(b)(4)

(b)(4)

[redacted]

[redacted]

(b)(4)

(b)(4)

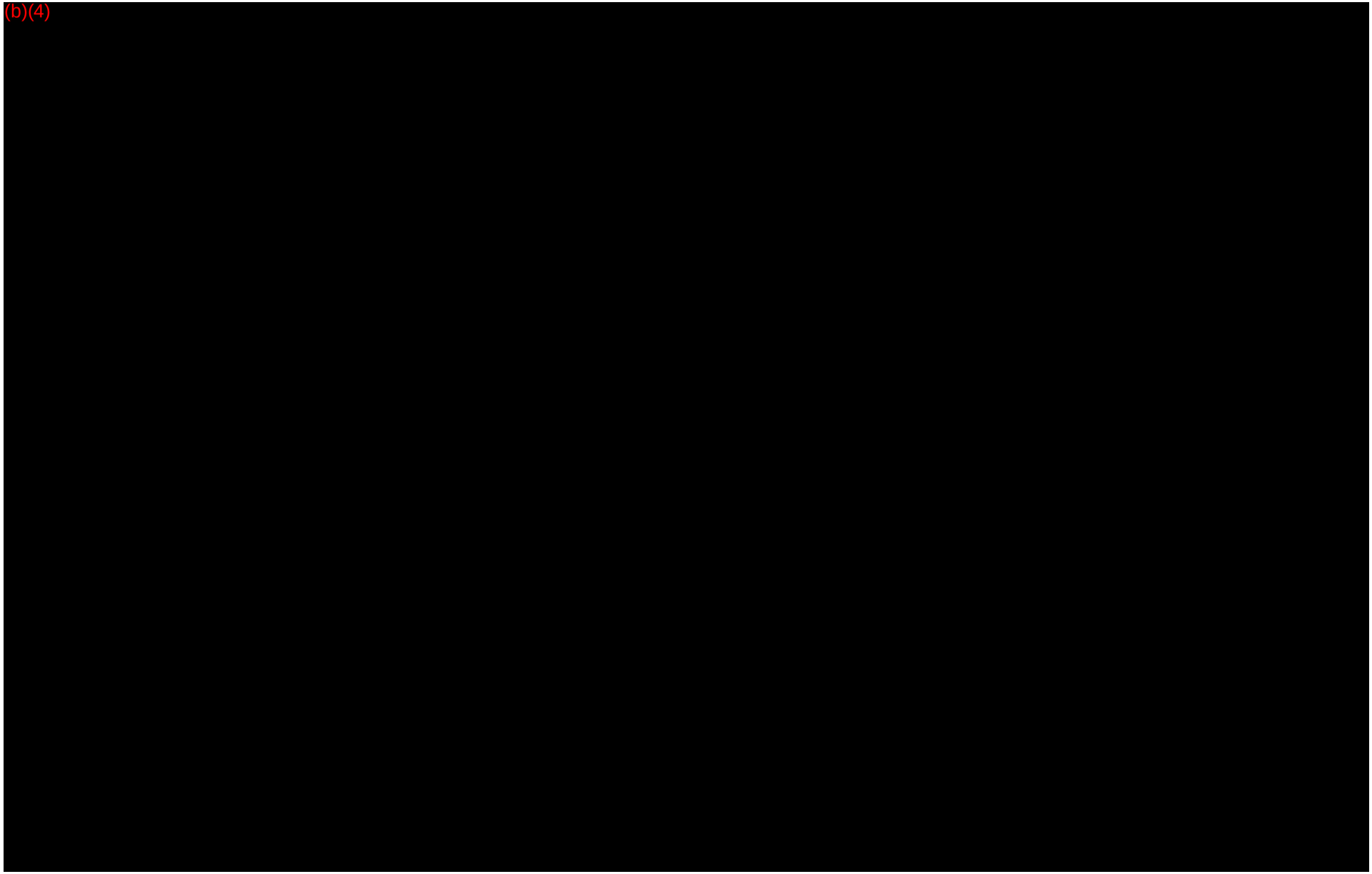
[redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)



[redacted]

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)

[redacted]

(b)(4)

Respire Pink Series – Herbst – EF

Testing Protocol – Material Integrity

Doc: (b)(4)

Rev(

Respire Medical
BREATHE EASY AGAIN

[redacted]

(b)(4)

Doc: (b)(4)

Rev: (

Respire Medical
BREATHE EASY AGAIN

Respire Pink Series – Herbst – EF

Testing Protocol – Material Integrity

[redacted]

(b)(4)

(b)(4)

(b)(4)

Doc: (b)(4)

Rev: [redacted]

Respire Medical
BREATHE EASY AGAIN

Respire Pink Series – Herbst – EF

Testing Protocol – Material Integrity

[redacted]

(b)(4)

Respire Pink Series – Herbst – EF

Testing Protocol – Material Integrity

Doc: (b)(4)

Rev(

Respire Medical
BREATHE EASY AGAIN

(b)(4)

(b)(4)

Doc: (b)(4)

Rev(

Respire Pink Series – Herbst – EF

Testing Protocol – Material Integrity

Respire Medical
BREATHE EASY AGAIN

(b)(4)

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

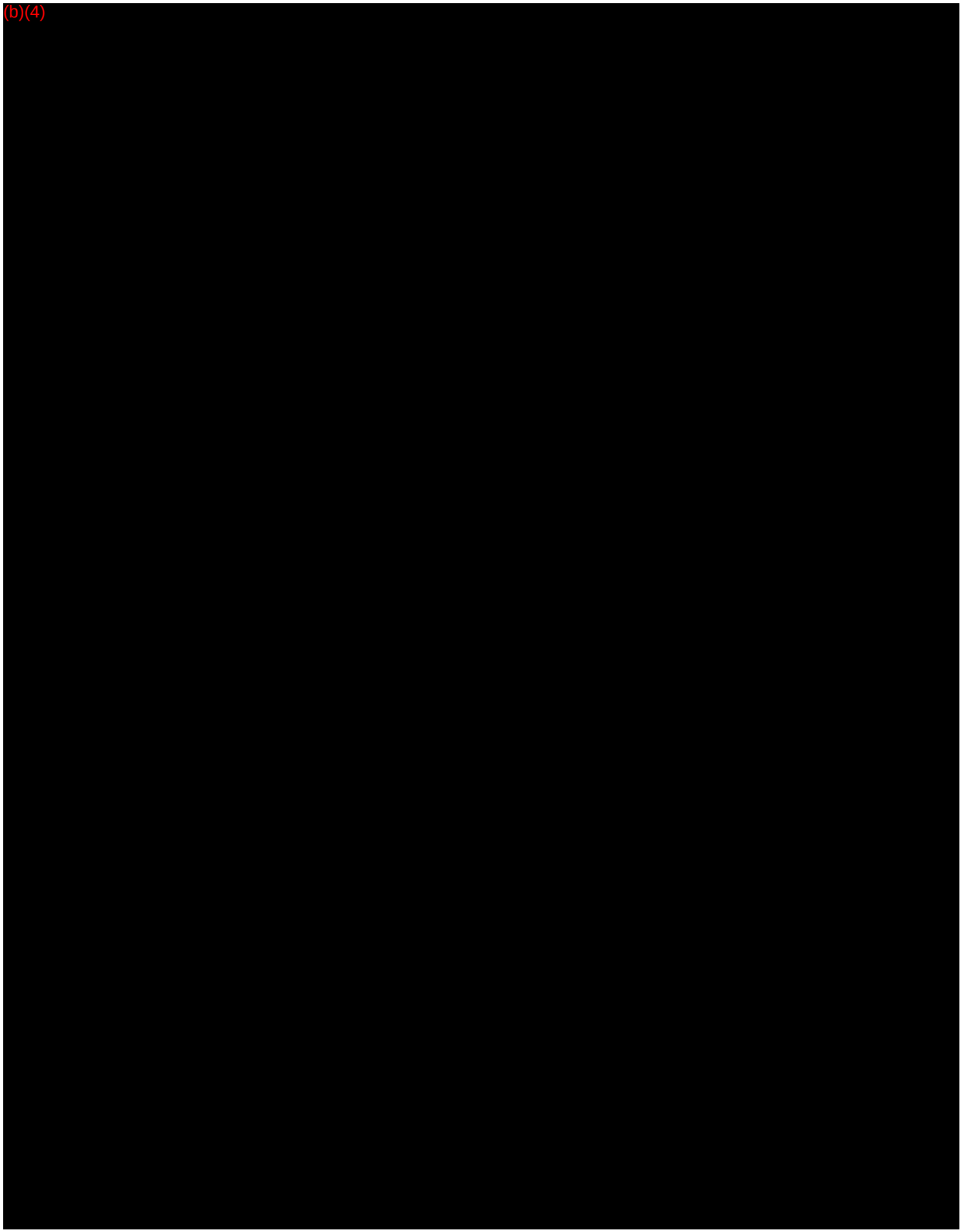
(b)(4)

[redacted]

(b)(4)

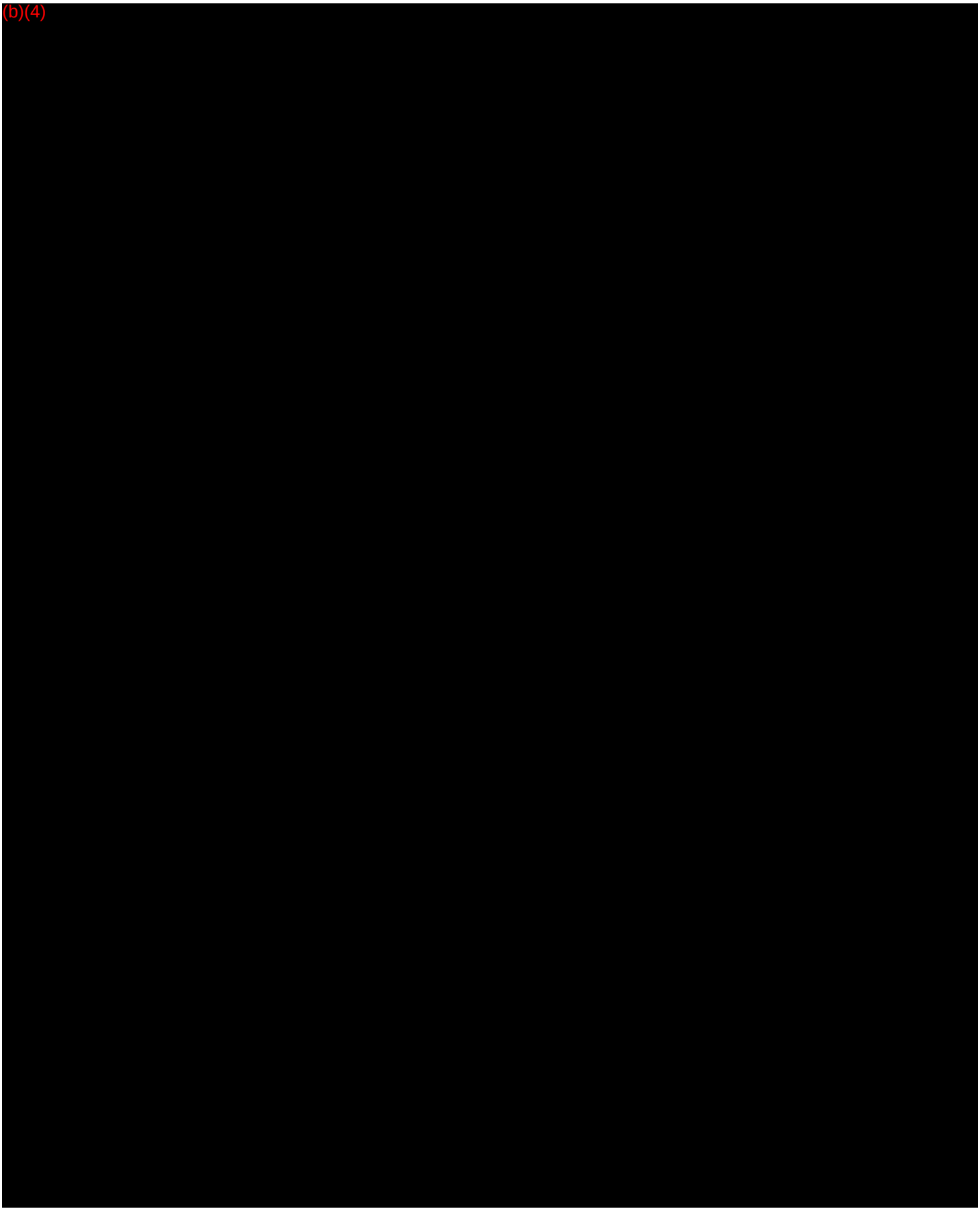
(b)(4)

(b)(4)

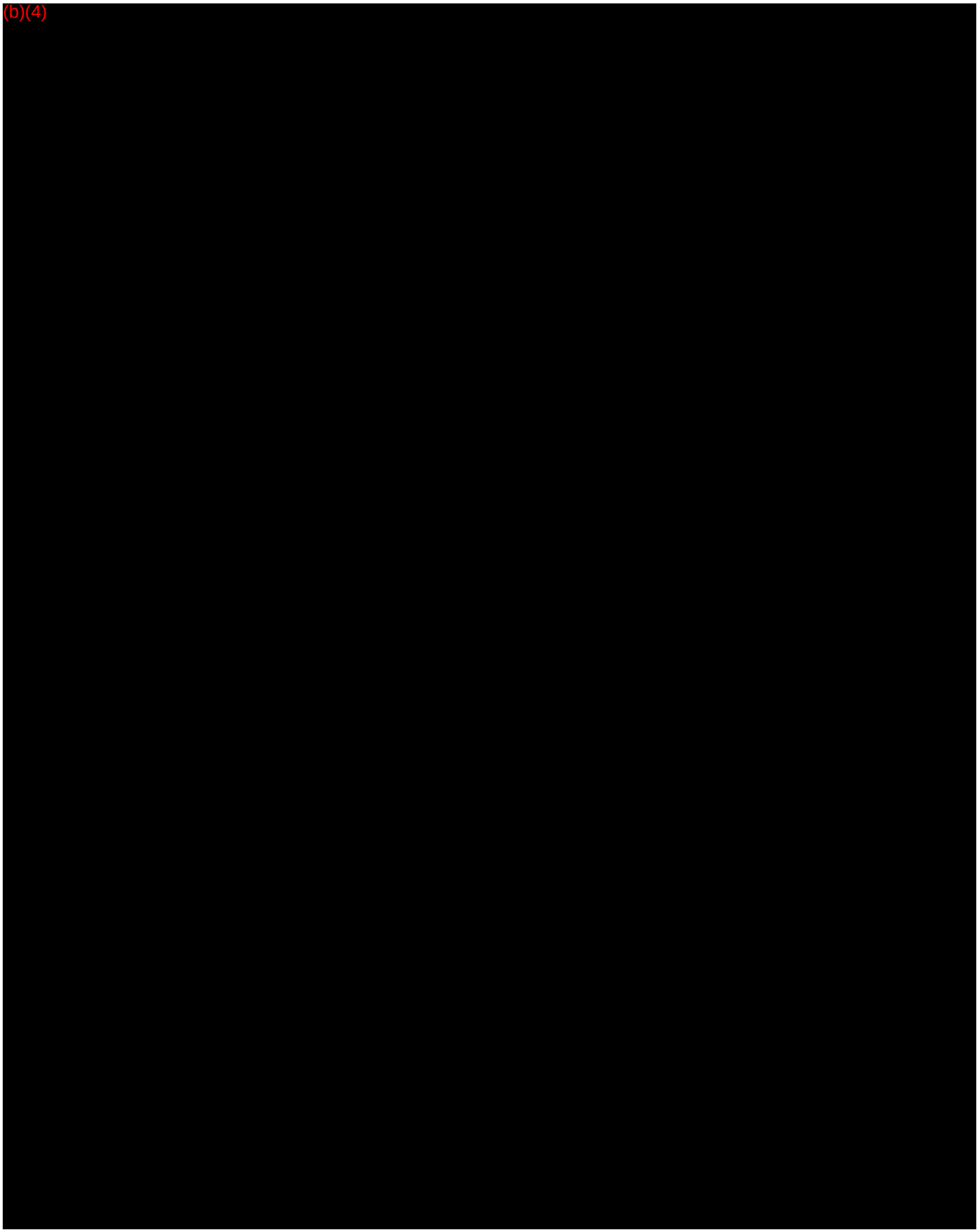


(b)(4)

(b)(4)



(b)(4)



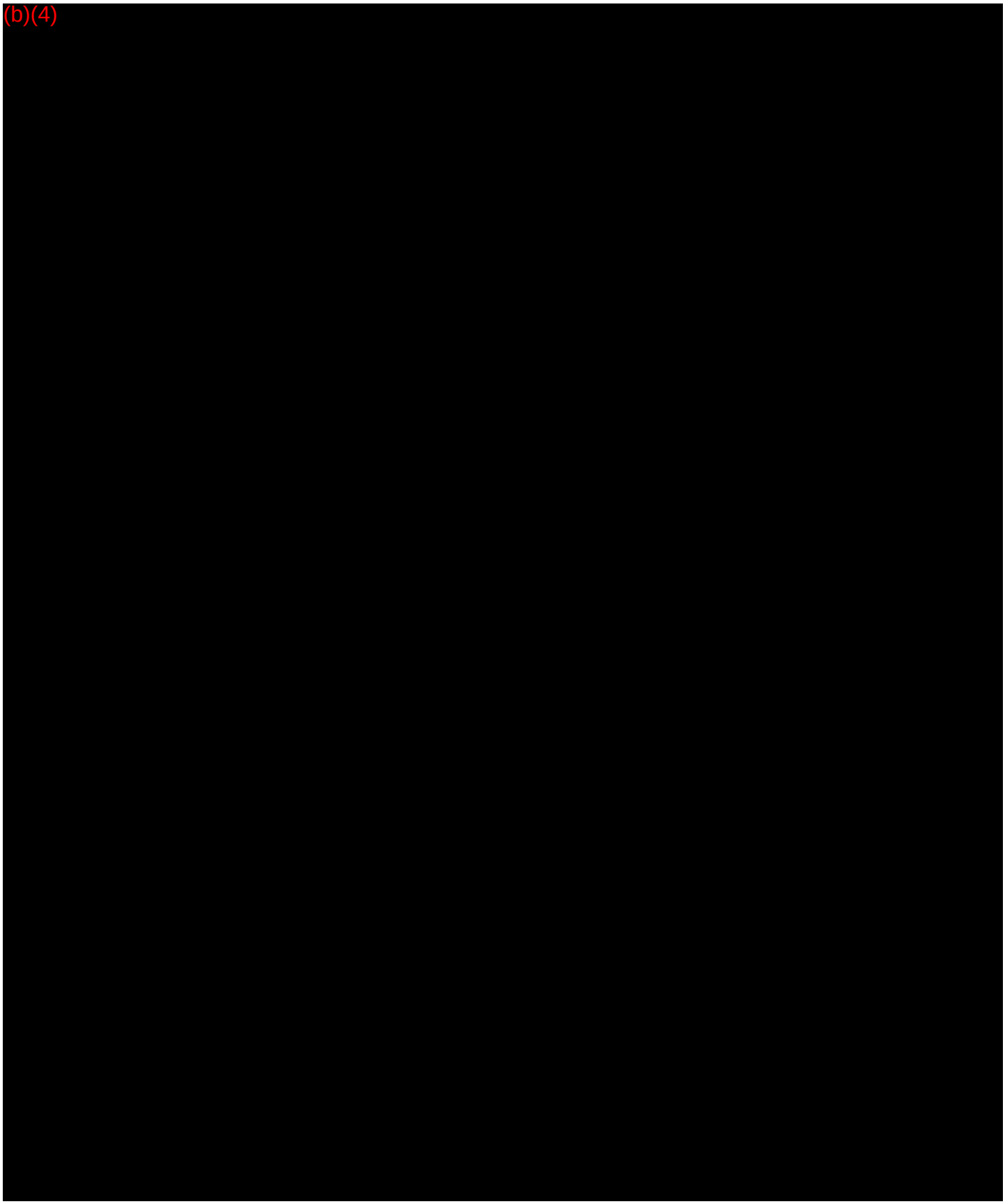
(b)(4)

K 150572 Attachment C

(b)(4)

K 150572 Attachment C

(b)(4)



(b)(4) [redacted]

Certificate

Biocompatibility Test

(b)(4) [redacted]

From: 510K Program
Sent: Friday, April 03, 2015 11:59 AM
To: Runner, Susan; 510K Program
Cc: Kiang, Tina; Freeman, Anike
Subject: RE: signed conversion NEED DECISION TODAY, THANK YOU! DAY 30

Susan,

I converted the submission from a Special to a Traditional due to inclusion of a new material that you have not seen before in this type of device that will require review of full test reports to support its safety and effectiveness (e.g., biocompatibility, etc.).

Please inform the company of this conversion, confirm dates have changed in CTS, and include a copy of this e-mail in Docman as a record of 510(k) Staff concurrence.

Michael Bailey, Ph.D.
CDRH/ODE/POS/510(k)
WO66 Room G120
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6530
michael.bailey@fda.hhs.gov<mailto:michael.bailey@fda.hhs.gov>

From: Runner, Susan
Sent: Friday, April 03, 2015 11:47 AM
To: 510K Program
Subject: FW: signed conversion NEED DECISION TODAY, THANK YOU! DAY 30
Importance: High

Susan [BD21295_]
Susan Runner, DDS, MA
Branch Chief Dental Devices
CDRH/FDA/ODE
WO-66-2538

10903 New Hampshire Ave
Silver Spring, MD 20993
Tel: 301-796-6282
Fax: 301-847-8109

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=436&E=&S=E

From: Kiang, Tina
Sent: Friday, April 03, 2015 11:41 AM
To: Runner, Susan
Cc: Freeman, Anike
Subject: RE: signed conversion

Here's the signed form. Please email 510(k) Staff to get their concurrence.

Tina Kiang, Ph.D.
Acting Deputy Director
Science and Policy
FDA/CDRH/ODE/DAGRID
301-796-5580
tina.kiang@fda.hhs.gov<mailto:tina.kiang@fda.hhs.gov>

From: Runner, Susan
Sent: Friday, April 03, 2015 11:36 AM
To: Kiang, Tina
Cc: Freeman, Anike
Subject: signed conversion
Importance: High

From: 510K Program
Sent: Friday, April 03, 2015 11:59 AM
To: Runner, Susan; 510K Program
Cc: Kiang, Tina; Freeman, Anike
Subject: RE: signed conversion NEED DECISION TODAY, THANK YOU! DAY 30

Susan,

I converted the submission from a Special to a Traditional due to inclusion of a new material that you have not seen before in this type of device that will require review of full test reports to support its safety and effectiveness (e.g., biocompatibility, etc.).

Please inform the company of this conversion, confirm dates have changed in CTS, and include a copy of this e-mail in Docman as a record of 510(k) Staff concurrence.

Michael Bailey, Ph.D.
CDRH/ODE/POS/510(k)
WO66 Room G120
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6530
michael.bailey@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: *https://www.research.net/s/cdrhcustomerservice?O=400&D=410&B=413&E=&S=E*

From: Runner, Susan
Sent: Friday, April 03, 2015 11:47 AM
To: 510K Program
Subject: FW: signed conversion NEED DECISION TODAY, THANK YOU! DAY 30
Importance: High

Susan -

Susan Runner, DDS, MA
Branch Chief Dental Devices
CDRH/FDA/ODE
WO-66-2538
10903 New Hampshire Ave
Silver Spring, MD 20993

Tel: 301-796-6282
Fax: 301-847-8109

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=436&E=&S=E

From: Kiang, Tina
Sent: Friday, April 03, 2015 11:41 AM
To: Runner, Susan
Cc: Freeman, Anike
Subject: RE: signed conversion

Here's the signed form. Please email 510(k) Staff to get their concurrence.

Tina Kiang, Ph.D.
Acting Deputy Director
Science and Policy
FDA/CDRH/ODE/DAGRID
301-796-5580
tina.kiang@fda.hhs.gov

From: Runner, Susan
Sent: Friday, April 03, 2015 11:36 AM
To: Kiang, Tina
Cc: Freeman, Anike
Subject: signed conversion
Importance: High

Dear Mr. Inglese,

I am writing to you as the lead reviewer of your submission for the Respire Pink Series Herbst EF. After conducting a review of the information presented, we have determined your device raises additional questions which would require additional data. Therefore, your submission has been converted to a traditional 510(k). You will be formally notified of deficiencies once I have finished compiling them; hopefully within the next week or two. No action need be taken by you at this time. Please let me know if you have any additional questions.

Sincerely,

Anike Freeman
Biomedical Engineer
FDA/CDRH/ODE/DAGRID
Dental Devices Branch
WO-66, Room 2556

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=436&E=&S=E

Dear Mr. Inglese,

I am writing to you as the lead reviewer of your submission for the Respire Pink Series Herbst EF. After conducting a review of the information presented, we have determined your device raises additional questions which would require additional data. Therefore, your submission has been converted to a traditional 510(k). You will be formally notified of deficiencies once I have finished compiling them; hopefully within the next week or two. No action need be taken by you at this time. Please let me know if you have any additional questions.

Sincerely,

Anike Freeman
Biomedical Engineer
FDA/CDRH/ODE/DAGRID
Dental Devices Branch
WO-66, Room 2556

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=436&E=&S=E

May 5, 2015</br></br> We have reviewed your submission K150572 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K150572 to:

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

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is November 1, 2015. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Anike Freeman, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

March 18, 2015</br></br>
Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K150572, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Anike Freeman.

 *** This is a system-generated email notification ***

```
August 27, 2015</br></br><p>We have completed our review. Please refer to
the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned
to your submission, Anike Freeman.</p>
<br><br><p>*** This is a system-generated email notification ***</p>
```

4.0 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 *See PRA Statement below.*

510(k) Number *(if known)*
NA K150572

Device Name
Respire Pink Series - Herbst - EF

Indications for Use *(Describe)*
The Respire Pink Series - Herbst - EF is indicated to treat mild to moderate OSA.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

August 27, 2015

Respire Medical Holding
c/o Mr. Stephen Inglese
Quality Solutions and Support, LLC
PO Box 8271
Holland, MI 49422

Re: K150572
Trade/Device Name: Respire Pink Series-Herbst-EF
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: July 27, 2015
Received: July 30, 2015

Dear Mr. Inglese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Please address the following deficiencies for K150572:

(b)(4)

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K150572 Date Received by DCC: Mar 6, 2015

Lead Reviewer: Anike Freeman

Branch: DEDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments?		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments?		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments?		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (**21 CFR 820.30(g)**), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	X	
Comments?		

Does the submission meet all 4 criteria above?

- (•) Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation.*		
	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist)	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.				
7) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
8) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	X			
B. Device Description				
9)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
11) A description of all device modification(s) including rationale for each modification.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Design Control Activities				
17) Design Control Activities Summary includes all of the following:				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.	X			
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	X			
c) Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."* *i.* Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. *ii.* Statement that manufacturing facility is in conformance with design control procedure requirements as specified in *21 CFR 820.30*. *iii.* Statement is signed by the individual responsible for these activities.	X			
E. Proposed Labeling (see also 21 CFR part 801)				
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	X			
19) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	X			

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Anike K. Freeman -S 2015.03.17 16:25:46 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-0609
Silver Spring, MD 20993-0002

Please address the following deficiencies for K150572:

(b)(4)

4.0 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
NA K150572

Device Name
Respire Pink Series - Herbst - EF

Indications for Use *(Describe)*
The Respire Pink Series - Herbst - EF is indicated to treat mild to moderate OSA.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

FORM FDA 3881 (8/14) Page 1 of 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K150572 - AINN

Date: May 5, 2015
To: The Record
From: Anike Freeman, Biomedical Engineer

Office: ODE
Division: DAGRID

510(k) Holder: Respire Medical LLC
Device Name: Respire Pink Series – Herbst - EF
Contact: Stephen Inglese
Phone: (954) 830-0051
Fax: N/A
Email: swi@qss-llc.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the *Respire Pink Series Herbst EF** into interstate commerce. The sponsor is seeking to make a material change to their previously cleared *Respire Pink Series Herbst* from K131138. The proposed device is a prescription class II device regulated under 21 CFR 872.5570 as an anti-snoring device and is listed under product code LRK.

The original submission for this device consists of Form FDA 3601 and 3514, cover letter, indications for use statement, 510(k) summary, truthful and accuracy statement, executive summary, device description, substantial equivalence discussion, summary of design control activities, proposed labeling, instructions for use, and Form FDA 3654.

The primary mode of action of this device is mandibular advancement to reduce snoring and treat OSA.

**EF stands for "Endurance Framework"*

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		

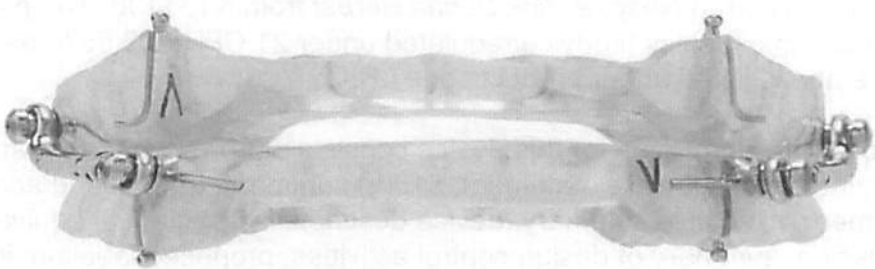
	Yes	No	N/A
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

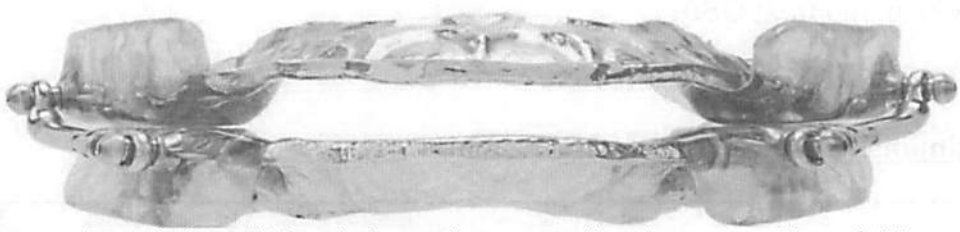
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?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

The proposed device is comprised of customized intraoral, upper and lower trays held together by a Herbst appliance. It is a mandibular advancement splint intended to hold the jaw in a forward position (advancement of up to 6mm). This device was previously cleared in K113138 with acrylic trays. In the new device, the sides remain acrylic and the middle portion will be made from wironit, a cobalt chromium alloy.** This is the only change to the device. Please see the images below for comparison.

K113138



Proposed Device:



**Please note there is insufficient information regarding the properties of this material. The sponsor claims it has been widely used in a number of dental

applications but has not identified any dental devices for which it has been cleared. This is addressed in the deficiencies.

IV. Indications for Use

The sponsor states:

"The Respire Pink Series – Herbst – EF is indicated to treat mild to moderate OSA (Obstructive Sleep Apnea)

This statement is identical to the one cleared in the K113138.

V. Predicate Device Comparison

As previously stated, the proposed device is a modified version of the sponsor's own predicate, K113138. The only change is to the middle section of the trays which will now be offered in wironit as opposed to acrylic. The sponsor has chosen to make this change because they want to offer patients a more comfortable fit and increase the device's durability. A substantial equivalence table, from the original 510(k) summary, is provided below.

Substantial Equivalence Topic	Respire Pink Series – Herbst	Respire Pink Series – Herbst - EF
510(k)	K131138	NA
Company Name	Respire Medical	Respire Medical
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)
Device Name	Device, Anti Snoring	Device, Anti Snoring
Product Code	LRK	LRK
Classification	Class II	Class II
Intended Use	The Respire Pink Series - Herbst is indicated to treat mild to moderate OSA.	The Respire Pink Series - Herbst – EF is indicated to treat mild to moderate OSA.
Single or Multiple Use	Multiple Use	Multiple Use
Target Population	Adult Patients	Adult Patients
Prescription or OTC Use	Prescription	Prescription

Device Components	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp
Appliance Design	Customized device Rigid tray two pieces Upper/Lower acrylic.	Customized device Rigid tray / two pieces / Upper and Lower / Acrylic and Wironit
Device Functionality	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep Upper and lower tray unhook for easy removal from mouth Works by mandibular advancement Adjustable using titration keys
Mandibular Advancement Range	6mm	6mm
Raw Material: Side / Upper and Lower Trays	Acrylic (side and upper and lower trays)	Acrylic (side) and Wironit (upper and lower trays)
Raw Material: Metal Components	Stainless Steel	Stainless Steel
Colorants	Pink	Pink

VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b). The sponsor has provided instructions for use which clearly highlight all changes to their original instructions for use. These documents are found in Appendix 2 of the original submission. These changes include:

- The addition of an image of the Pink Series EF
- An additional contraindication for patients who are "allergic to chrome (Wironit)"

- A statement that "The EF's all chrome anterior allows for additional lingual space and durability"

The statement regarding increased durability has not yet been substantiated. Please see the Bench Testing section for further discussion.

VII. Sterilization/Shelf Life/Reuse

The appliance will be supplied non-sterile to the user. However, the sponsor has not identified any further information on the cleaning and storage of their device or if there may be changes to the cleaning protocol because of the wironit material. This is addressed in the deficiencies.

VIII. Biocompatibility

The sponsor has provided MSD sheets and biocompatibility testing for their device. The MSDS states that Wironit is a metal alloy made up of 61% cobalt, 26% chromium, 6% molybdenum, and 5% tungsten. The sponsor conducted biocompatibility testing per ISO 10993 and provided test reports for cytotoxicity, skin irritation and sensitization. The reports demonstrate that the wironit material is non-cytotoxic and a non-irritant. As additional support, the sponsor will be asked to identify legally marketed, relevant dental devices which also utilize this material (as claimed in this submission).

IX. Software

There is no software included or used in this submission nor is it applicable for this device.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The proposed device does not appear to produce an EM field, utilize electricity, or produce a thermal effect. Therefore, EMC, mechanical safety, electrical safety, and thermal safety are not applicable.

XI. Performance Testing – Bench

Bench testing was not performed on this device. However, the reviewer has concerns regarding the claimed durability of the device. The device description and images provided do not adequately describe how the wironit anterior portion of the tray is connected to the acrylic sides. The strength of this connection is also unknown. Since acrylic and wironit are different materials, the interface between them may be weakened over time with repeated use. Information on the construction and mechanical performance of the device are critical to this review and are requested in the deficiencies.

In Appendix 3, the sponsor provides a complete risk analysis as recommended in the guidance. The risk analysis references ISO 14971:2007 – Medical devices – Application of risk management to medical devices. The characteristic table clearly identifies potential issues with the product, potential safety issues, and how those issues will be addressed.

XII. Performance Testing – Animal

This submission does not contain any animal testing data. This type of information is not applicable for this submission.

XIII. Performance Testing – Clinical

This submission does not contain any clinical testing data. This type of information is not applicable for this submission.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			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?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

XV. Deficiencies

1. In your device description you state you have replaced the anterior portion of your device's trays with a material known as "wironit." However, based on the images you have provided, it is unclear how the wironit piece is connected to the acrylic sides of the tray. Is it embedded in the acrylic or will the patient's molars also be in direct contact with the metallic portion? It is important for FDA to understand how the device is constructed and whether or not this construction is mechanically stable. Please address the following:
   a. Please clarify how the two materials are connected to each other and provide images of this connection.
   b. Please provide comparative bench testing demonstrating the interface of the acrylic and metallic portions of the device will not negatively impact the device's performance when compared to the original, all acrylic design. For example, you may want to consider testing the bend strength of the trays.
2. In your device description you state this new design offers patients increased comfort because it "reduces the thickness in the anterior portion" of the trays. However, you have not stated the thickness of the metallic section of the tray. This information is important in order to establish a more complete device description. Please state the thickness of the wironit component of your device.
3. Throughout your submission, you state wironit is a biocompatible material which has a history of use in a variety of dental devices. However, it is unclear which devices you are referencing. Please provide the 510(k) numbers of some of the relevant dental devices which also utilize this material.
4. Your submission does not contain a section on sterilization and shelf-life. While it is understood this device will be provided non-sterile and is non-sterile when used, it is unclear whether or not cleaning and storage conditions are affected by the change in material composition of your device. Please clarify whether or not the cleaning protocol and storage conditions for your device have changed. If it has changed, please provide cleaning validation or a justification for why cleaning validation is not necessary. If it has remained the same, please provide justification as to why your design change does not warrant a change in how your device is cleaned and stored.

XVI. Contact History

May 5

The reviewer notified the sponsor of the deficiencies and placed the file on hold.

XVII. Recommendation - AINN

Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: Class II
Product Code: LRK

Digital Signature Concurrence Table	
Reviewer Sign-Off	Anike K. Freeman -S 2015.05.05 14:38:06 -04'00'

Food and Drug Administration
CDRH/ODE/DAGID/DEDB
WO66 RM2556
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-7617

Premarket Notification [510(k)] Review

Date: August 26, 2015

Reviewer: Anike Freeman

Subject: Traditional 510(k)# K150572/S001

Applicant: Respire Medical Holding	**Device Trade Name:** Respire Pink Series-herbst-ef
Contact Name: Stephen Inglese	**Contact Title:** Founder And CEO
Correspondent Firm: Quality Solutions And Support, LLC	**Phone:** (954) 830-0051 **Email:** swi@qss-llc.com
Received Date: July 30, 2015	**Due Date:** August 29, 2015
Reg #: 872.5570 **Reg Name:** Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea	**Class:** II **Product Code(s):** LHR

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K131138	LRK	Respire Pink Series - Herbst	Respire Medical

Review Summary

The subject device is a Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea with the following Indications for Use: "The Respire Pink Series - Herbst - EF is indicated to treat mild to moderate OSA (Obstructive Sleep Apnea)" It is for Rx use.

Recommendation

I recommend that the Respire Pink Series-herbst-ef is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer Anike Freeman (CDRH/ODE/DAGRID/DEDB)

I. Purpose and History

TPLC Information Recall Information Historyfalls

The 510(k) holder would like to introduce the *Respire Pink Series Herbst EF** into interstate commerce. The sponsor is seeking to make a material change to their previously cleared *Respire Pink Series Herbst* from K131138. The proposed device is a prescription Class II device regulated under 21 CFR 872.5570 as an anti-snoring device and is listed under product code LRK.

The original submission for this device consists of Form FDA 3601 and 3514, cover letter, indications for use statement, 510(k) summary, truthful and accuracy statement, executive summary, device description, substantial equivalence discussion, summary of design control activities, proposed labeling, instructions for use, and Form FDA 3654.

The primary mode of action of this device is mandibular advancement to reduce snoring and treat OSA.

**EF stands for "Endurance Framework"*

II. Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☐	☒	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☐	☒	☐
The device/system uses or is	a reusable single patient use device(s)		☐
Is the device a combination product?	N - Not a Part 3 Combination Product		☐
Is the device electrical (battery or wall powered)?	No, the device is not electrical		☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

Device Description Table: Summary of important device characteristics

The proposed device is comprised of customized intraoral, upper and lower trays held together by a Herbst appliance. It is a mandibular advancement splint intended to hold the jaw in a forward position (advancement of up to 6mm). This device was previously cleared in K113138 with completely acrylic trays. In the new device, the sides remain acrylic and the middle portion will be made from wironit, a cobalt chromium alloy. This is the only change to the device. The sponsor has chosen to make this change to allow the patient more lingual space for added comfort. Please see the images below for comparison.

The wironit material has been used in a variety of other dental devices. It is connected to the acrylic via a process known as co-molding or co-casting and the wironit mesh is embedded into the acrylic for additional stability (see below).

Proposed Device:

K113138:

Reviewer Recommendation
The Device Description is acceptable.

III. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K150572 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☒	☐	☐	☐	☐
No	☒	☒	☒	☐	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use: "The Respire Pink Series – Herbst – EF is indicated to treat mild to moderate OSA (Obstructive Sleep Apnea)"

Predicate(s)

Submission#: K131138 Rx/OTC: Rx

Intended Population:

Indications for Use: The respire pink series - herbst is indicated to treat mild to moderate osa. Prescription

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation
The Comparison of the Indications for Use is acceptable. **The indications for use are identical to the selected predicate.**

IV. Comparison of Technology to Predicate Devices

As previously stated, the proposed device is a modified version of the sponsor's own predicate, K113138. The only change is to the middle section of the trays which will now be offered in wironit as opposed to acrylic. The sponsor has chosen to make this change because they want to offer patients a more comfortable fit and while maintaining the device's durability. A substantial equivalence table, from the original 510(k) summary, is provided below. Concerns regarding potential mechanical effects of the change in material are adequately addressed by bench testing and discussed in Section X of this review.

Substantial Equivalence Topic	**Respire Pink Series – Herbst**	**Respire Pink Series – Herbst - EF**
510(k)	K131138	NA
Company Name	Respire Medical	Respire Medical
Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)
Device Name	Device, Anti Snoring	Device, Anti Snoring
Product Code	LRK	LRK

Classification	Class II	Class II
Intended Use	The Respire Pink Series - Herbst is indicated to treat mild to moderate OSA.	The Respire Pink Series - Herbst – EF is indicated to treat mild to moderate OSA.
Single or Multiple Use	Multiple Use	Multiple Use
Target Population	Adult Patients	Adult Patients
Prescription or OTC Use	Prescription	Prescription
Device Components	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp	Orthodontic Acrylic trays, Telescopic Herbst Hardware and Ball Clasp
Appliance Design	Customized device Rigid tray two pieces Upper/Lower acrylic.	Customized device Rigid tray / two pieces / Upper and Lower / Acrylic and Wironit
Device Functionality	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep. Upper and lower tray unhook for easy removal from mouth. Works by mandibular advancement. Adjustable using titration keys.	Allows to increase pharyngeal opening, and to improve the ability to exchange air during sleep Upper and lower tray unhook for easy removal from mouth Works by mandibular advancement Adjustable using titration keys
Mandibular Advancement Range	6mm	6mm
Raw Material: Side / Upper and Lower Trays	Acrylic (side and upper and lower trays)	Acrylic (side) and Wironit (upper and lower trays)
Raw Material: Metal Components	Stainless Steel	Stainless Steel
Colorants	Pink	Pink

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

V. Labeling

Labeling Review Needed?	Yes	No
Usability Consult Needed?	Yes	No

A General Labeling Requirements

General Labeling Requirements	Yes	No|N/A	Inadequate or Marked

General Labeling Requirements	Yes	No|N/A	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
The indications for use are consistent with the IFU page?	☒	☐	☐
Appropriate contraindications provided?	☒	☐	☐
Appropriate warnings provided?	☒	☐	☐
Instructions are in accordance with the guidance (if applicable)?	☒	☐	☐
Appropriate labeling inside device?	☒	☐	☐
Appropriate label/indicator outside device?	☒	☐	☐
Appropriate Manual labeling?	☒	☐	☐
What MRI safety information does the labeling contain?	Not Evaluated and Not Needed		☐

Labeling Table: A summary of the adequacy of several labeling requirements.

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b). The sponsor has provided instructions for use which clearly highlight all changes to their original instructions for use. These documents are found in Appendix 2 of the original submission and the changes include:

- The addition of an image of the Pink Series EF
- An additional contraindication for patients who are "allergic to chrome (Wironit)"
- A statement that "The EF's all chrome anterior allows for additional lingual space and durability"

The statements regarding increased lingual space and durability were not originally substantiated. In S001, the sponsor provided additional testing to support this statement. Please see the Bench Testing section for further discussion. Aside from these changes, the instructions for use are the same as the predicate. It includes instructions for both the clinician and patient. Step by step instructions are provided on how to place and remove the appliance. It also explicitly states that any adjustments to the device are to be made by the clinician. Finally, there are instructions which adequately describe device cleaning and storage conditions. The reviewer has no additional concerns regarding the labeling for this device.

Reviewer Recommendation

The Labeling is acceptable.

VI. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

The appliance will be supplied non-sterile to the user. The patient is to clean the device daily with soap and cool water. Once a week, they are instructed to soak the device in a commercial denture or orthodontic cleaner for 5 minutes. When not in use, it is to be stored in the provided protective case. These are the same cleaning instructions as the predicate and consistent with the cleaning instructions provided for other previously cleared oral appliances made from similar materials.

There is no shelf-life for this device. It is made to order and given to the patient shortly after manufacture. The acrylic and metallic components of the trays are not expected to degrade.

Reviewer Recommendation
Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VII. Biocompatibility

Biocompatibility Review Needed?	Yes	No
Biocompatibility Consult Needed?	Yes	No

The sponsor has provided material safety data sheets and a summary of biocompatibility testing for their device. The MSDS states Wironit is a metal alloy made up of 61% cobalt, 26% chromium, 6% molybdenum, and 5% tungsten. The sponsor included biocompatibility test reports per ISO 10993 for cytotoxicity, skin irritation and sensitization. The summary reports come from the material manufacturer and state the wironit material is non-cytotoxic and a non-irritant. As additional support, the sponsor was asked to identify legally marketed, relevant dental devices which also utilize this material (as claimed in this submission). In S001 they identified several other devices which the reviewer has verified as containing cobalt chromium alloys such as wironit. These devices include two oral appliances, the Luco Hybrid OSA Appliance (K130797) and the Therasom-Cast (K113516). The reviewer was satisfied with the comparisons drawn to these devices as they contain cobalt-chromium alloys of similar composition and have similar indications.

The acrylic used to fabricate this device is identical to that of the predicate. Additionally, the wironit material is essentially a cobalt-chromium alloy which the sponsor has adequately identified as being used in other oral appliances. Finally, there is no expectation of a chemical interaction between the acrylic and metallic components of this device. Therefore, the reviewer has concluded that new biocompatibility testing is not necessary.

Reviewer Recommendation
The Biocompatibility is acceptable.

VIII. Software/Firmware

There is no software included or used in this submission nor is it applicable for this device.

Reviewer Recommendation
The Software is **[not]** acceptable.

IX. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

The proposed device does not appear to produce an EM field, utilize electricity, or produce a thermal effect. Therefore, EMC, mechanical safety, electrical safety, and thermal safety are not applicable.

Reviewer Recommendation
The EMC, EMT and Risk Analysis are **[not]** acceptable.

X. Performance Testing

A Bench Testing

To address concerns regarding the strength of connection between the acrylic and wironit portions of the tray, the sponsor conducted tensile strength tests on all acrylic and acrylic embedded with wironit samples. The sponsor tested 5 samples of each and averaged the measured tensile strength values. They also evaluated elongation to

failure. The test report is provided in Appendix B of S001 and a summary of the results is provided in the table below:

Summary of Results – Data / Averaged

Material	Elongation to failure	Ultimate Tensile Strength (lbf)	Load Failure	Analysis of Failure
Acrylic	.217 inches	453.4	453.4	Brittle
Wironit / Acrylic	.114 inches	275.6	275.6	Brittle

The results demonstrated a significant difference in tensile strength between the subject and predicate devices. However, the sponsor has provided adequate justification for why the result is still acceptable. In the deficiency response letter, found in S001, the sponsor cites the work of Dr. Ali Nankali who studied masticatory forces and determined that the average force generated during routine mastication was about 110-160 lbf which is still significantly lower than the forces the wironit appliance design can withstand. The reviewer is in agreement with the sponsor's assertions. Furthermore, a lower tensile strength is expected since the acrylic sample was one continuous material and the wironit sample is composed of two dissimilar materials, metal embedded in acrylic.

To demonstrate the wironit appliance offers more lingual space, the sponsor measured the thickness of the anterior portion of the appliance. Please see the images below.

Figure 1 – A

Predicate – Respire Pink Series – Herbst

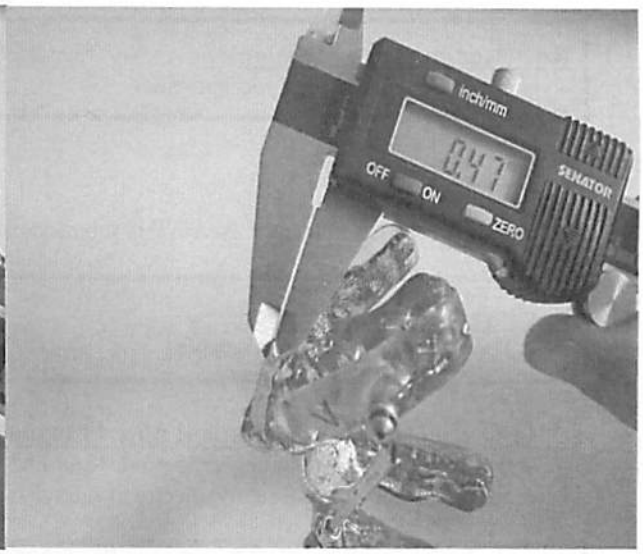


Figure 1 - B

Respire Pink Series – Herbst – EF

The measurements clearly show a reduction in thickness of almost 2 mm, demonstrating that the proposed device does in fact offer the patient more lingual space. The sponsor has adequately justified the claims of increased lingual space. The sponsor has also adequately supported the durability claims of their device with the previously discussed

bench testing. They have shown that even though the metallic anterior is thinner than the acrylic, it is still mechanically stable enough to withstand loads of the oral cavity. The reviewer has no additional comments.

Finally, per the *Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea*, the sponsor provided a risk analysis. Documentation of this analysis was provided in Appendix 3 of the original submission using a product risk analysis worksheet. This analysis clearly identifies a comprehensive list of potential risks, identifies them by characteristic category, and states their relation to the overall safety of the device. It also evaluates the severity of each risk and identifies a risk control action to be taken should such a risk occur. The risk analysis appears to be complete. The reviewer has no additional questions regarding this document.

B Animal Testing
Not applicable.

C Clinical Testing
Not applicable.

Reviewer Recommendation
The Performance Testing is acceptable.

XI. Kit Certification
Not applicable

XII. Manufacturing Information
Not applicable

XIII. References
Not applicable

XIV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: The intended use of the subject device is identical to that of the selected predicate.		
Do the devices have the same technological characteristics?	☐	☒
Please describe the different technological characteristics: The subject device uses a metallic material, wironit, in the anterior region of the tray to offer the patient more lingual space while still maintaining its mechaincal durability		
Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	☐	☒
Are the methods acceptable?	☒	☐
Do the data demonstrate equivalence and support the Indications for Use?	☒	☐
Please explain how the data do or do not demonstrate substantial equivalence: The bench testing provided shows that changing the material composition of the device does not affect is ability to withstand loads typical of the oral cavity. The sponsor has also adequately supported claims of biocompatibility and identified other oral appliances which utilize cobalt-chromium alloys.		

XV. Original Deficiencies

1. In your device description you state you have replaced the anterior portion of your device's trays with a material known as "wironit." However, based on the images you have provided, it is unclear how the wironit piece is connected to the acrylic sides of the tray. Is it embedded in the acrylic or will the patient's molars also be in direct contact with the metallic portion? It is important for FDA to understand how the device is constructed and whether or not this construction is mechanically stable. Please address the following:

   a. Please clarify how the two materials are connected to each other and provide images of this connection.

   b. Please provide comparative bench testing demonstrating the interface of the acrylic and metallic portions of the device will not negatively impact the device's performance when compared to the original, all acrylic design. For example, you may want to consider testing the bend strength of the trays.

2. In your device description you state this new design offers patients increased comfort because it "reduces the thickness in the anterior portion" of the trays. However, you have not stated the thickness of the metallic section of the tray. This information is important in order to establish a more complete device description. Please state the thickness of the wironit component of your device.

3. Throughout your submission, you state wironit is a biocompatible material which has a history of use in a variety of dental devices. However, it is unclear which devices you are referencing. Please provide the 510(k) numbers of some of the relevant dental devices which also utilize this material.

4. Your submission does not contain a section on sterilization and shelf-life. While it is understood this device will be provided non-sterile and is non-sterile when used, it is unclear whether or not cleaning and storage conditions are affected by the change in material composition of your device. Please clarify whether or not the cleaning protocol and storage conditions for your device have changed. If it has changed, please provide cleaning validation or a justification for why cleaning validation is not necessary. If it has remained the same, please provide justification as to why your design change does not warrant a change in how your device is cleaned and stored.

XVI. Contact History

May 5, 2015
The reviewer notified the sponsor of the deficiencies and placed the file on hold.

July 26, 2015
The sponsor provided responses to each of the deficiencies as follows.

1. Clarification on device description and additional bench testing:
   a. The sponsor provided additional images of the underside of the tray to show how the wironit component was embedded in the acrylic. They also identified the process for bonding the two materials as a co-casting/co-molding procedure. The reviewer was satisfied with this explanation.

b. The sponsor provided comparative bench testing reports on the tensile strength of the acrylic vs acrylic-wironit combination. Even though the results for the acrylic-wironit samples were lower, the overall strength was still higher than typical masticatory forces. The reviewer found this response to be acceptable.

2. The sponsor provided measurements of the anterior lingual thickness of appliance trays. The measurements showed a significant decrease in thickness from 3.39 to 0.47 mm. The reviewer believes the sponsor's claims regarding lingual space have been substantiated.
3. The sponsor provided the biocompatibility certificate from the material manufacturer along with MSDS sheets demonstrating that the materials used to make wironit are not new or unusual to dental devices. They also provided the 510(k) numbers of previously cleared oral appliances which also utilize cobalt chromium alloys. These responses were acceptable.
4. The sponsor elaborated on the cleaning and maintenance of the device now that it contains an additional component. They explained that the cleaning procedures remain the same as the predicate's and also identified other previously cleared oral appliances made using cobalt-chromium materials which follow similar cleaning protocols. The reviewer found this response to be acceptable.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Anike K. Freeman -S 2015.08.26 09:52:14 -04'00'