

**510(k) SUMMARY***[As required by 21 CFR 807.92(c)]*

K090244

**Date Prepared** January 30<sup>th</sup>, 2009

**Official Contact** Mr. Steven Lubke,  
Regulatory Affairs Director **APR 13 2009**

**Device Trade Name** Swift™ FX

**Device Common Name/  
Classification Name** Vented Nasal Mask;  
Accessory to Noncontinuous Ventilator (IPPB)

**Classification** 21 CFR 868.5905, 73 BZD (Class II)

**Predicate Devices** Swift LT (K073638)  
Ultra Mirage II Mask (K050359)

**Description** The Swift FX provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face.

Swift FX is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

Swift FX is a prescription device supplied nonsterile.

**Intended Use** The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The Swift FX is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

**Technological Characteristics comparison** Comparison with predicate Swift LT  
The new device and the predicate mask, provide a seal via silicone interface. Both masks are offered in various sizes to ensure adequate fit over the extended patient population.

Both the masks incorporate vent holes to provide continuous air leak to flush out and minimize the amount of CO<sub>2</sub> rebreathed by the patient. The design of the mask components is such that the incorporation of these vent-holes does not interfere with the intended performance of the masks.

Both the masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004)

Both the masks are constructed using molded plastic and silicone components and fabric / nylon headgear. All the

January 30, 2009

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components of both the masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

Both the new device and the predicate are designed to operate on the same *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both the new device and the predicate device are substantially equivalent.

Both the new device and the predicate device can be reused in the home and hospital / institution environment.

The main differences between Swift FX and Swift LT is in the number of components, their design/geometry and how individual components interface with each other. Both masks are designed and constructed under ResMed's 21 CFR Part 820 compliant Quality Management System.

**Clinical Data** Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the Swift FX, as was the case with the predicate device.

**Performance Data** *Comparison with predicate Ultra Mirage II*  
The CO2 performance of the new device and the predicate device are substantially equivalent.

**Substantial Equivalence Conclusion** Swift FX is substantially equivalent to the predicate devices:

- it has the same intended use;
- it has similar technological characteristics to both predicates;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective as the predicate devices Swift LT and Ultra Mirage II



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

ResMed Limited  
C/o Mr. David D'Cruz  
Resmed Corporation  
14040 Danielson Street  
Poway, California 92064-6857

APR 13 2009

Re: K090244  
Trade/Device Name: Swift™ FX  
Regulation Number: 21 CFR 868.5905  
Regulatory Class: II  
Product Code: BZD  
Dated: January 30, 2009  
Received: February 2, 2009

Dear Mr. D'Cruz:

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 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.

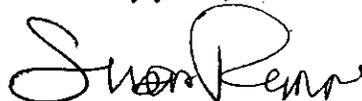
Page 2- Mr. D'Cruz

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., MA  
Acting Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indication for Use**

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

**Device Name:** Swift™ FX

**Indication for Use**

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)  
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

*Susan Kumar*

Page 1 of   1  

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

510(k) Number:   K090244



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

ResMed Limited  
C/o Mr. David D'Cruz  
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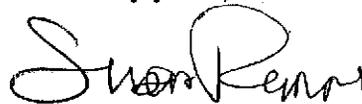
Page 2- Mr. D'Cruz

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Sincerely yours,



Susan Runner, D.D.S., MA  
Acting Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**RESMED**

Swift FX  
Traditional 510k

**Indication for Use**

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

Device Name: **Swift™ FX**

Indication for Use

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

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

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510(k) Number:   K090244



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

February 02, 2009

RESMED LTD.  
C/O RESMED CORP.  
14040 DANIELSON ST.  
POWAY, CALIFORNIA 92064-6857  
UNITED STATES  
ATTN: DAVID D'CRUZ

510k Number: K090244  
Received: 2/2/2009  
Product: SWIFT FX

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

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HIDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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

([http://www.fda.gov/oc/initiatives/fdaaa/guidance\\_certifications.html](http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html)). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at [www.fda.gov/cdrh/ode/guidance/1567.html](http://www.fda.gov/cdrh/ode/guidance/1567.html). Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice [www.fda.gov/cdrh/devadvice/](http://www.fda.gov/cdrh/devadvice/). If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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

AN/DAGID

K090244

**RESMED**

Swift FX  
Traditional 510k

FDA CDRH DMC

January 30<sup>th</sup>, 2009

Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

FEB 2 2009

Received

Attention: Office of Device Evaluation, Div of Anesthesiology, Infection Control, and Dental Devices

**Re: Traditional 510(k) Notification (21 CFR 807.90(e)) for a New Device.**

Ladies and Gentlemen,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act), as amended, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, this 510(k) Premarket Notification is being submitted to advise the Food and Drug Administration (FDA) of intent to commercially distribute the medical device, Swift™ FX.

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

ResMed submits that the Swift FX is Substantially Equivalent to the predicate devices, Swift LT (K073638) and Ultra Mirage II Mask (K050359) and recommends that the classification is 21 CFR §868.5905 (Product Code 73 BZD, Class II device).

This submission is a Traditional 510(k) as indicated on our Premarket Submission Cover Sheet.

Summary of principal aspects of *Design and Use of the Device* in accordance with the *Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s: August 12, 2005- Appendix A:*

Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	No
Does the device contain components derived from a tissue or other biologic source?	No
Is the device provided sterile?	No
Is the device intended for single use?	No
Is the device a reprocessed single use device?	No
If yes, does this device type require reprocessed validation data?	No
Does the device contain a drug?	No
Does the device contain a biologic?	No
Does the device use software?	No
Does the submission include clinical information?	No
Is the device implanted?	No

January 30, 2009

**RESMED**

Swift FX  
Traditional 510k

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The contents of this submission is confidential commercial information and we request that they be protected from public disclosure to the full extent permitted by the provisions of 21 CFR §20.61 and 21 CFR §807.95. We understand that the submission to the United States Government of false information is prohibited by Title 18 of the United States Code (USC) Part 1001, and Title 21 of the USC Part 331(q).

If you have any questions, please do not hesitate to contact David D'Cruz (davidd@resmed.com or (858) 746-2238) at our USA office or Kim Lee (kiml@resmed.com.au or +61 2 8884 1000) at our Australian office.

Yours sincerely,

*Steven Kulle*  
*fr*

DIRECTOR - REGULATORY AFFAIRS

30 JANUARY, 2009.

Dr Lionel King  
V.P., Quality Assurance & Regulatory Affairs. ResMed Ltd.

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January 30, 2009

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**RESMED**

Swift FX  
Traditional 510K

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## **1. Medical Device User Fee Cover Sheet (FDA FORM 3601)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
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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)  RESMED 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 AU 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) NO DATA	2. CONTACT NAME Greg Dockar 2.1 E-MAIL ADDRESS GregD@resmed.com.au 2.2 TELEPHONE NUMBER (include Area code) 61 2-8884 2175 2.3 FACSIMILE (FAX) NUMBER (Include Area code) +61 2-8884
---	---

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

<p><u>Select an application type:</u></p> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	<p>3.1 Select a center  <input checked="" type="checkbox"/> CDRH  <input type="checkbox"/> CBER</p> <p>3.2 <u>Select one of the types below</u>  <input checked="" type="checkbox"/> Original Application  <u>Supplement Types:</u>  <input type="checkbox"/> Efficacy (BLA)  <input type="checkbox"/> Panel Track (PMA, PMR, PDP)  <input type="checkbox"/> Real-Time (PMA, PMR, PDP)  <input type="checkbox"/> 180-day (PMA, PMR, PDP)</p>
--	--

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

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:

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?

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.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
---	--

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES                       NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

15-Dec-2008





**RESMED**

Swift FX  
Traditional 510K

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## **2. CDRH Premarket Review Submission Cover Sheet**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 FOOD AND DRUG ADMINISTRATION

Form Approval  
 OMB No. 9010-0120  
 Expiration Date: May 31, 2007.  
 See OMB Statement on page 5.

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission <b>Jan 30, 2009</b>	User Fee Payment ID Number <b>(b)(4)</b>	FDA Submission Document Number (if known) —
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 <b>ResMed Ltd</b>	Establishment Registration Number (if known) <b>3004604967</b>		
Division Name (if applicable) <b>N/A</b>	Phone Number (including area code) <b>+61 2 8884 1000</b>		
Street Address <b>1, Elizabeth Macarthur Drive,</b>	FAX Number (including area code) <b>+ 61 2 8883 3114</b>		
City <b>Bella Vista</b>	State / Province <b>NSW</b>	ZIP/Postal Code <b>2153</b>	Country <b>Australia</b>
Contact Name <b>Kim Lee</b>			
Contact Title <b>Regulatory Affairs Manager, Patient Interface Division.</b>		Contact E-mail Address <b>kiml@resmed.com.au</b>	

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

Company / Institution Name <b>ResMed Corp (2183969)</b>	Phone Number (including area code) <b>(858) 746 2238</b>		
Division Name (if applicable) <b>N/A</b>	FAX Number (including area code) <b>(858) 746 2915</b>		
Street Address <b>14040 Danielson St</b>	FAX Number (including area code) <b>(858) 746 2915</b>		
City <b>Poway</b>	State / Province <b>CA</b>	ZIP/Postal Code <b>92064 6857</b>	Country <b>USA</b>
Contact Name <b>Mr David D'Cruz</b>			
Contact Title <b>V.P., Clinical &amp; Regulatory Affairs</b>		Contact E-mail Address <b>davidd@resmed.com</b>	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	73 BZD	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K073638	1	Swift LT	1	ResMed
2	K050359	2	Ultra Mirage II	2	ResMed
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  
**Vented Nasal Mask for use with Noncontinuous Ventilator (IPPB)**

	Trade or Proprietary or Model Name for This Device		Model Number
1	Swift FX	1	No model number available
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 <b>BZD</b>	C.F.R. Section (if applicable) <b>868.5905</b>	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel <b>73 Anesthesiology</b>		

Indications (from labeling)

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX is:

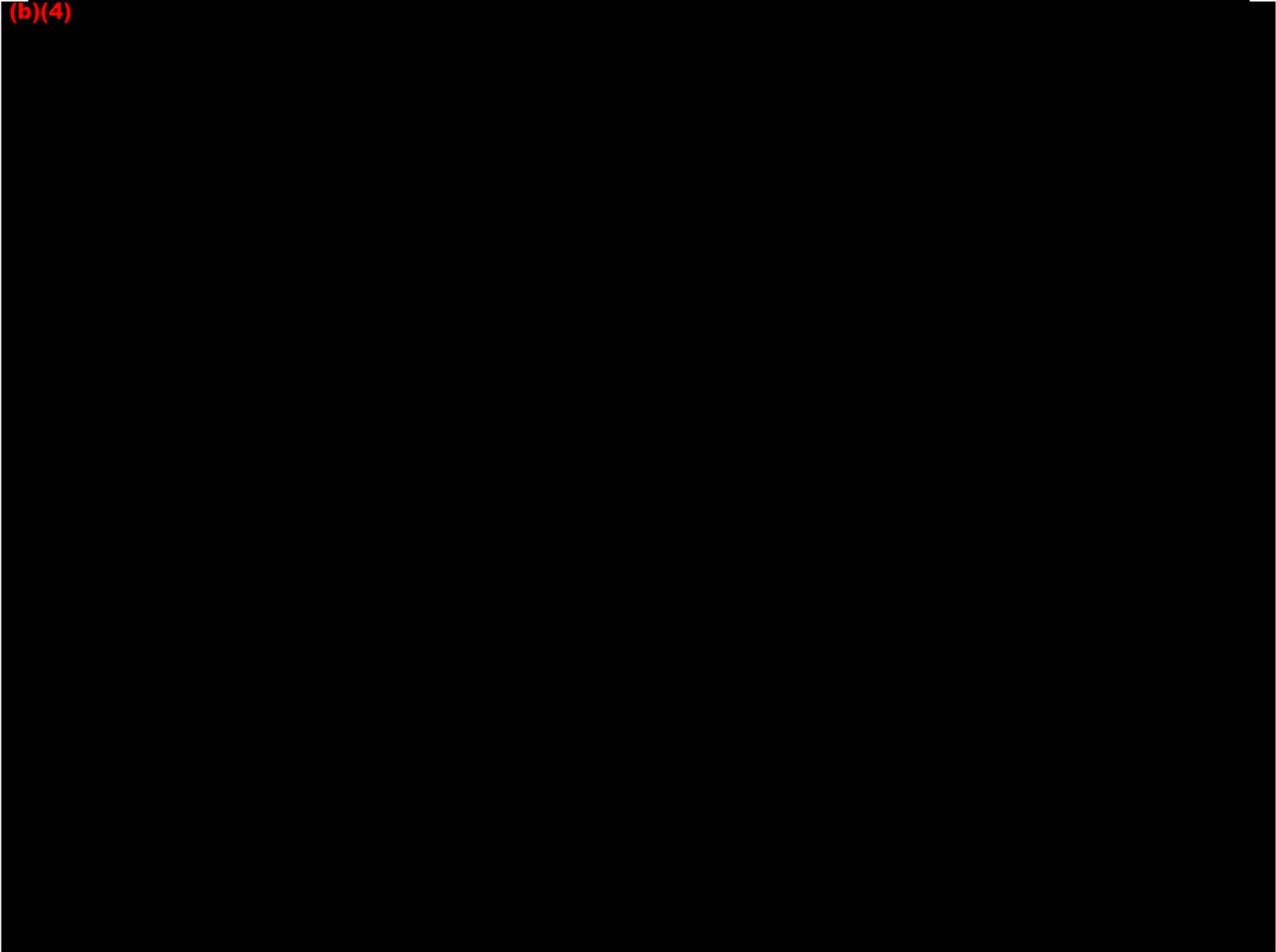
- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

**(b)(4)**



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) (    )		
Street Address			FAX Number (including area code) (    )		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

**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.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	14971	ISO	Medical devices -- Application of risk management to medical devices	1	2000
2	10993-1	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing	3	2003
3	5356-1	ISO	Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets	3	2004
4					
5					
6					
7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
CDRH (HFZ-342)  
9200 Corporate Blvd.  
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*

**RESMED**

Swift FX  
Traditional 510K

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### **3. 510(k) Cover Letter**

**RESMED**Swift FX  
Traditional 510kJanuary 30<sup>th</sup>, 2009

Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

**Attention:** Office of Device Evaluation, Div of Anesthesiology, Infection Control, and Dental Devices

**Re: Traditional 510(k) Notification (21 CFR 807.90(e)) for a New Device.**

Ladies and Gentlemen,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act), as amended, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, this 510(k) Premarket Notification is being submitted to advise the Food and Drug Administration (FDA) of intent to commercially distribute the medical device, **Swift™ FX**.

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

ResMed submits that the Swift FX is Substantially Equivalent to the predicate devices, Swift LT (K073638) and Ultra Mirage II Mask (K050359) and recommends that the classification is 21 CFR §868.5905 (Product Code 73 BZD, Class II device).

This submission is a Traditional 510(k) as indicated on our Premarket Submission Cover Sheet.

Summary of principal aspects of *Design and Use of the Device* in accordance with the *Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s: August 12, 2005- Appendix A:*

Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	No
Does the device contain components derived from a tissue or other biologic source?	No
Is the device provided sterile?	No
Is the device intended for single use?	No
Is the device a reprocessed single use device?	No
If yes, does this device type require reprocessed validation data?	No
Does the device contain a drug?	No
Does the device contain a biologic?	No
Does the device use software?	No
Does the submission include clinical information?	No
Is the device implanted?	No

January 30, 2009

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**RESMED**

Swift FX  
Traditional 510k

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The contents of this submission is confidential commercial information and we request that they be protected from public disclosure to the full extent permitted by the provisions of 21 CFR §20.61 and 21 CFR §807.95. We understand that the submission to the United States Government of false information is prohibited by Title 18 of the United States Code (USC) Part 1001, and Title 21 of the USC Part 331(q).

If you have any questions, please do not hesitate to contact David D'Cruz (davidd@resmed.com or (858) 746-2238) at our USA office or Kim Lee (kiml@resmed.com.au or +61 2 8884 1000) at our Australian office.

Yours sincerely,

*Steven Kulle*  
*for*

DIRECTOR - REGULATORY AFFAIRS

30 JANUARY, 2009.

Dr Lionel King  
V.P., Quality Assurance & Regulatory Affairs. ResMed Ltd.

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January 30, 2009

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***RESMED***

Swift FX  
Traditional 510K

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## **4. Indications for Use**



Swift FX  
Traditional 510k

### Indication for Use

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

Device Name: **Swift™ FX**

**Indication for Use**

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

Prescription Use   **X**    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

**RESMED**

Swift FX  
Traditional 510K

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## **5. 510(k) SUMMARY**

**510(k) SUMMARY***[As required by 21 CFR 807.92(c)]*

<b>Date Prepared</b>	January 30 <sup>th</sup> , 2009
<b>Official Contact</b>	Mr. Steven Lubke, Regulatory Affairs Director
<b>Device Trade Name</b>	Swift™ FX
<b>Device Common Name/ Classification Name</b>	Vented Nasal Mask; Accessory to Noncontinuous Ventilator (IPPB)
<b>Classification</b>	21 CFR 868.5905, 73 BZD (Class II)
<b>Predicate Devices</b>	Swift LT (K073638) Ultra Mirage II Mask (K050359)
<b>Description</b>	<p>The Swift FX provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face.</p> <p>Swift FX is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.</p> <p>Swift FX is a prescription device supplied nonsterile.</p>
<b>Intended Use</b>	<p>The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The Swift FX is:</p> <ul style="list-style-type: none"> <li>• to be used by adult patients (&gt; 66 lb/30 kg) for whom positive airway pressure has been prescribed</li> <li>• intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.</li> </ul>
<b>Technological Characteristics comparison</b>	<p><u><i>Comparison with predicate Swift LT</i></u> The new device and the predicate mask, provide a seal via silicone interface. Both masks are offered in various sizes to ensure adequate fit over the extended patient population.</p> <p>Both the masks incorporate vent holes to provide continuous air leak to flush out and minimize the amount of CO<sub>2</sub> rebreathed by the patient. The design of the mask components is such that the incorporation of these vent-holes does not interfere with the intended performance of the masks.</p> <p>Both the masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004)</p> <p>Both the masks are constructed using molded plastic and silicone components and fabric / nylon headgear. All the</p>

components of both the masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

Both the new device and the predicate are designed to operate on the same *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both the new device and the predicate device are substantially equivalent.

Both the new device and the predicate device can be reused in the home and hospital / institution environment.

The main differences between Swift FX and Swift LT is in the number of components, their design/geometry and how individual components interface with each other. Both masks are designed and constructed under ResMed's 21 CFR Part 820 compliant Quality Management System.

**Clinical Data** Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the Swift FX, as was the case with the predicate device.

**Performance Data** *Comparison with predicate Ultra Mirage II*  
The CO2 performance of the new device and the predicate device are substantially equivalent.

**Substantial Equivalence Conclusion** Swift FX is substantially equivalent to the predicate devices:

- it has the same intended use;
- it has similar technological characteristics to both predicates;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective as the predicate devices Swift LT and Ultra Mirage II

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Swift FX  
Traditional 510K

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## **6. Premarket Notification Truthful and Accurate Statement**

**RESMED**

Swift FX  
Traditional 510k

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**Premarket Notification Truthful and Accurate Statement**

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as V.P., Quality Assurance & Regulatory Affairs of ResMed Ltd., 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.

*Steven Pulke*  
for

DIRECTOR - REGULATORY AFFAIRS

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(Signature)

Dr Lionel King

(Typed Name)

30 JANUARY, 2009.

(Date)

Not Available

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(Premarket Notification [510(k)] Number)

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January 30, 2009

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**RESMED**

Swift FX  
Traditional 510K

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## **7. Class III Summary and Certification**

The Swift FX is not a Class III Device. ResMed has determined that it is a Class II device, 21 CFR 868.5905, 73 BZD.

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Swift FX  
Traditional 510K

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## **8. Financial Certification or Disclosure Statement**

No financial certification is required.

No clinical studies were needed to demonstrate *Substantial Equivalence*.

**RESMED**

Swift FX  
Traditional 510K

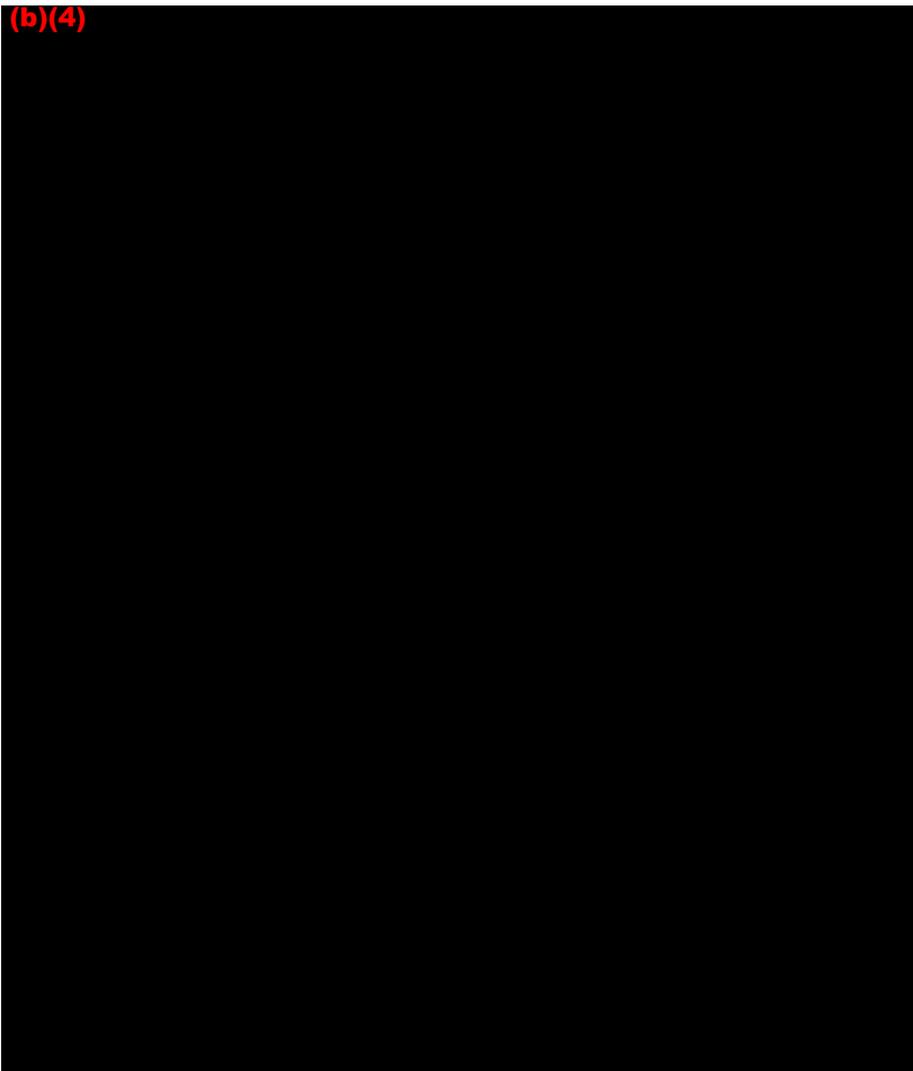
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## **9. Declarations of Conformity and Summary Reports**

The Swift FX is a Traditional 510(k) submission. No Declarations of Conformity or summary reports are required.

## 10. Executive Summary

ResMed intends to market the Swift FX nasal mask as a multi patient reuse device in the USA. The new device is substantially equivalent to the predicate devices Swift LT (K073638) and Ultra Mirage II Mask (K050359) also manufactured by ResMed.



ResMed believes the Swift FX is a medical device classified under 21 CFR 868.5905, 73 BZD (class II). It is a prescription device supplied nonsterile.

The Swift FX provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face. Swift FX is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

**Intended Use Statement**

***Predicate Device:*** The Swift LT channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.  
***Swift LT (K073638)***

The Swift LT is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed.
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

***Secondary predicate:*** The Ultra Mirage II Nasal Mask is intended for multipatient use for adult patients prescribed continuous positive airway pressure (CPAP) or bilevel therapy in hospital, clinic, and/or home environments.  
***Ultra Mirage II (K050359)***

***New Device:*** The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.  
***Swift FX***

The Swift FX is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

**Substantial Equivalence Summary**

The differences and similarities between the new device and the predicate devices are summarised below:

***Intended use*** Both the Swift LT and Ultra Mirage II masks have the same intended use as the Swift FX mask.

***Technological Characteristics*** *Comparison with predicate Mirage Swift*  
The new device and the predicate mask, provide a seal via silicone interface. Both masks are offered in various sizes to ensure adequate fit over the extended patient population.

Both the masks incorporate vent holes to provide continuous air leak to flush out and minimize the amount of CO<sub>2</sub> rebreathed by the patient. The design of the mask components is such that the incorporation of these vent-holes does not interfere with the intended performance of the masks.

Both the masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004)

Both the masks are constructed using molded plastic and silicone components and fabric / nylon headgear. All the components of both the masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

Both the new device and the predicate are designed to operate on the same *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both the new device and

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the predicate device are substantially equivalent.

Both the new device and the predicate device can be reused in the home and hospital / institution environment.

The main differences between Swift FX and Mirage Swift is in the number of components, their design/geometry and how individual components interface with each other. Both the masks are designed and constructed under ResMed's 21 CFR Part 820 compliant Quality Management System.

**Clinical Data** Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the Swift FX, as was the case with the predicate device.

**Performance Data** *Comparison with predicate Ultra Mirage II*  
The CO2 performance of the Swift FX have been demonstrated to be substantially equivalent to the Ultra Mirage II.

**Substantial  
Equivalence  
Conclusion** Swift FX is substantially equivalent to the predicate devices:

- it has the same, though reworded intended use;
- it has similar technological characteristics to both predicates;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective as the predicate devices Swift LT and Ultra Mirage II.

## **Performance Summary**

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The performance criteria designed to demonstrate substantial equivalence of the new device to its predicate including the overall results (pass/fail) are summarised below:

*CO2 flushing:*

**(b)(4)**

*Mask  
Characteristics:*

*Assembly  
Integrity:*

*Material Safety:*

*Multi patient  
Multi use*

*Transportation  
and Storage:*

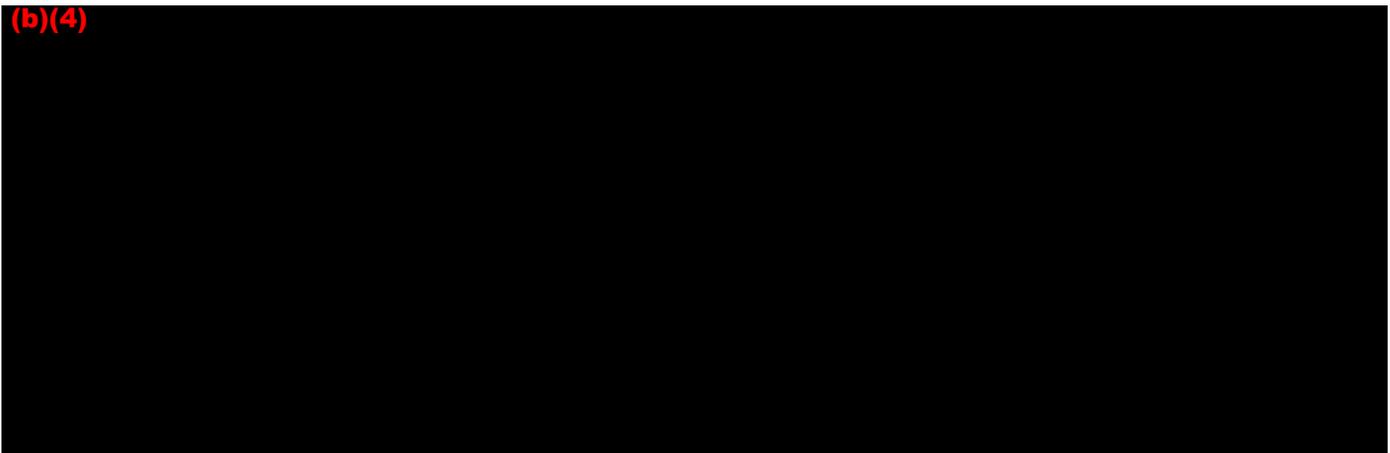
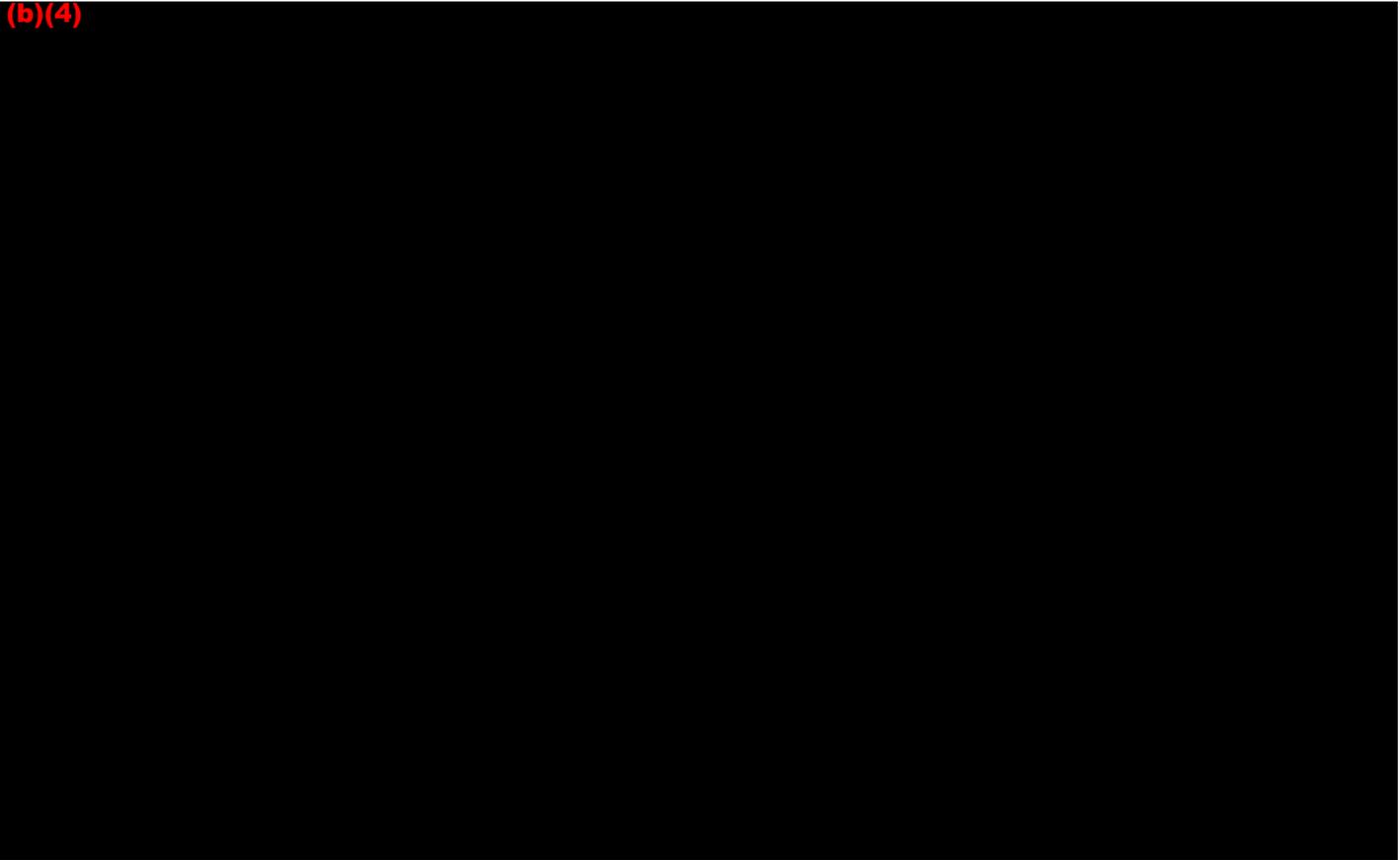
**RESMED**

Swift FX  
Traditional 510K

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## 11. Device Description

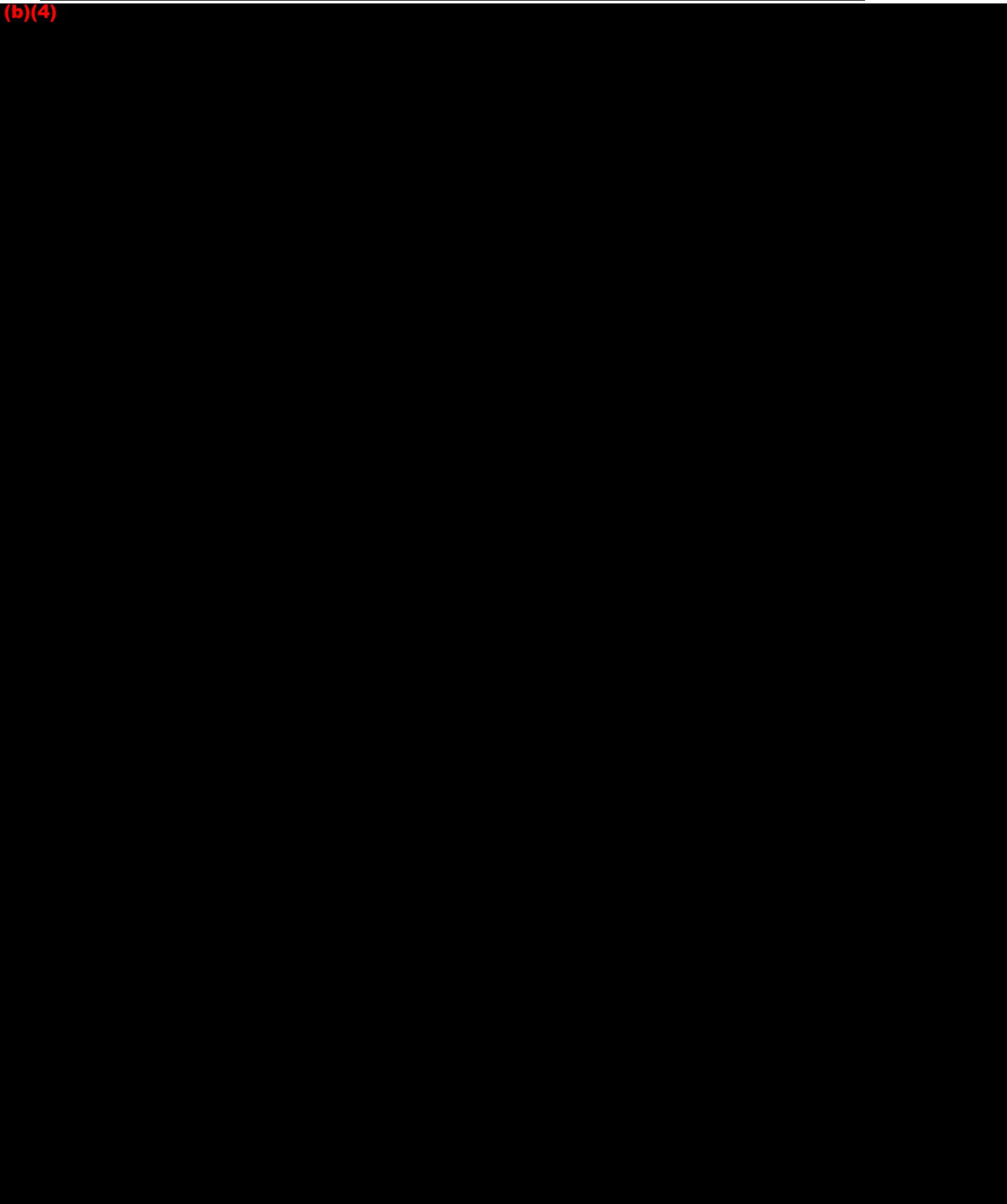
Continuous Positive Airway Pressure (CPAP) and bilevel systems are used for the treatment of adult Obstructive Sleep Apnea (OSA) and/or ventilatory support. In the majority of patients on CPAP or bilevel therapy, pressurized air can be supplied effectively via nasal masks. The Swift FX is intended for such patients.



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Swift FX  
Traditional 510K

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January 30, 2009

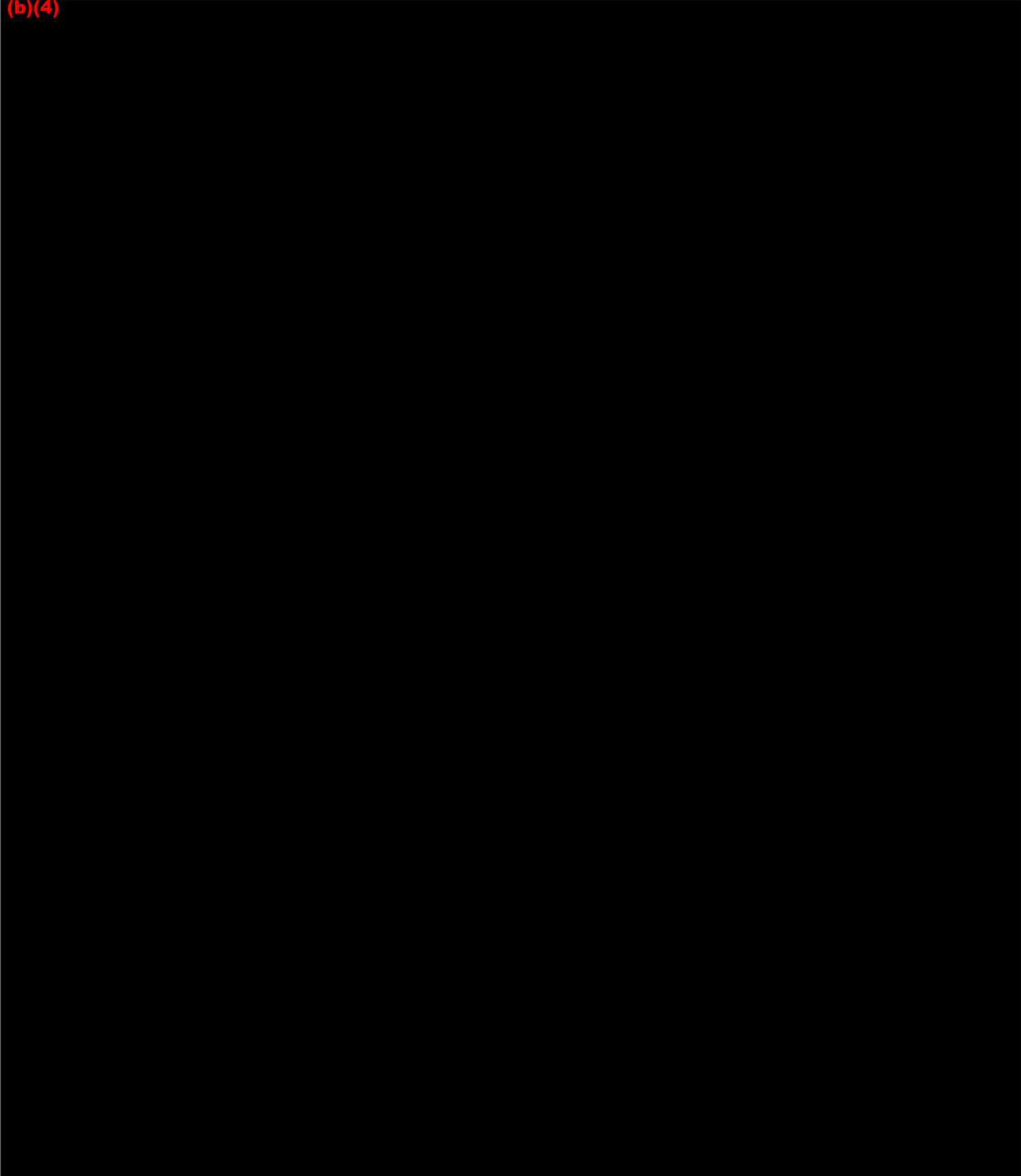
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Swift FX  
Traditional 510K

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January 30, 2009

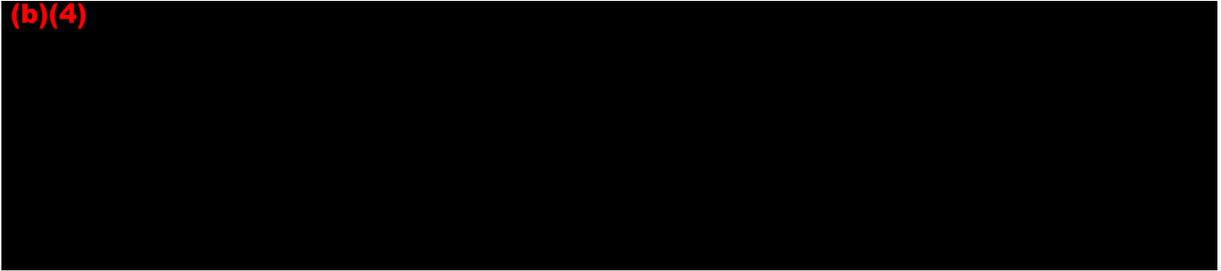
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Swift FX  
Traditional 510K

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**(b)(4)**



## 12. Discussion on Substantial Equivalence

### Comparison of the Swift FX to the Swift LT (K073638 )

The following tables are provided to identify the similarities and differences between the new mask and predicate device. Detailed protocols and pass/fail criteria are provided in section 18.

	New Device : <b>Swift FX</b>	Predicate Device: <b>Swift LT (K073638)</b>	<b>Comparison</b>
<p><i>Indication For Use Statement</i></p> <p><b>SUBSTANTIALLY EQUIVALENT</b></p>	<p>(b)(4)</p>	<p>The Swift LT channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.</p> <p>The Swift LT is:</p> <ul style="list-style-type: none"> <li>to be used by adult patients (&gt; 66 lb/30 kg) for whom positive airway pressure has been prescribed.</li> <li>intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.</li> </ul>	<p>The new device has the same / identical intended use as the predicate device.</p>
<p><i>Safety</i></p> <p><b>SUBSTANTIALLY EQUIVALENT</b></p>		<p>Incorporate vent holes to provide continuous air leak to flush out the dead space CO<sub>2</sub> and minimize it from being rebreathed by the patient. The design of the mask components is such that the incorporation of these vent-holes do not interfere with the intended performance of the masks.</p> <p>All the components are fabricated using materials deemed safe. (ref: ISO 10993).</p> <p>Swift LT is a prescription only device.</p>	<p>The new device does not raise new questions of safety when compared to the predicate device.</p> <p>The new device is at least as safe as the predicate device.</p>

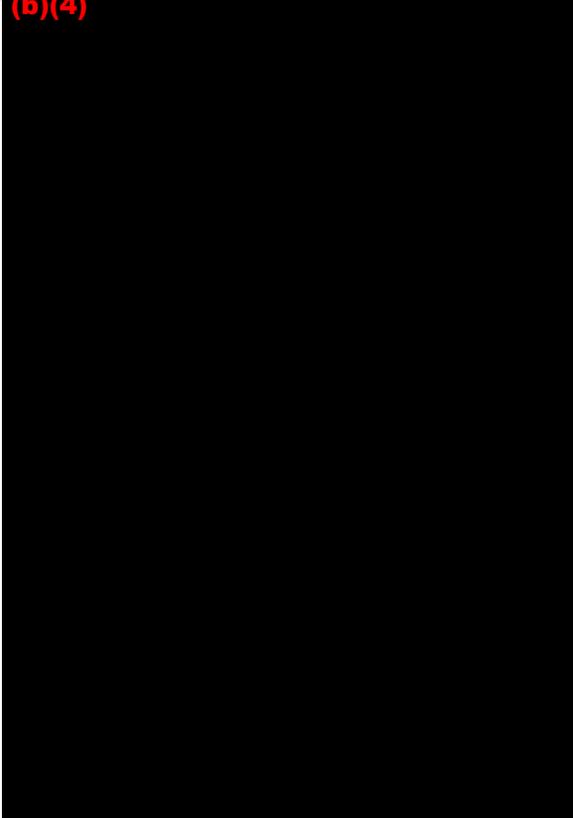
**RESMED**

Swift FX  
Traditional 510k

	New Device : <b>Swift FX</b>	Predicate Device: <b>Swift LT (K073638)</b>	<b>Comparison</b>
<p><i>Technological Characteristics</i></p> <p><b>SUBSTANTIALLY EQUIVALENT</b></p>	<p><b>(b)(4)</b></p>	<p>The Swift LT design incorporates a dual wall nasal pillow that covers the nasal nares to provide seal such that airflow from a positive pressure source is directed to the patient's nose.</p> <p>The mask is held in place with adjustable headgear that straps the mask to the face.</p> <p>The Swift LT is offered in three nasal pillow sizes; together with the adjustable headgear incorporating velcro tabs and straps, the mask fits a wide range of patient population.</p> <p>The mask includes an elbow which is able to rotate through 360°. The elbow &amp; short tube assembly connects to a conventional air delivery hose via 22mm conical connectors. (ref: ISO 5356-1).</p> <p>Swift LT is constructed using molded plastic and silicone components and fabric / nylon headgear.</p>	<p>The new device and the predicate mask have the same technological characteristics.</p> <p>The main differences between Swift FX and Swift LT are in the number of components, their design/geometry and how individual components interface with each other.</p>
<p><i>Performance</i></p> <p><b>SUBSTANTIALLY EQUIVALENT</b></p>		<p>Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing was sufficient to demonstrate safety and efficacy of the Swift LT.</p>	<p>The performance of the new device is substantially equivalent to the predicate device.</p>



Swift FX  
Traditional 510k

	New Device : Swift FX	Predicate Device: Swift LT (K073638)	Comparison
	<p>(b)(4)</p> 	<p>The flow at 4cm H2O is 21 L/min The flow at 10cm H2O is 31 L/min</p> <p>Drop in pressure measured (nominal) at 50 L/min: 0.62 cm H2O at 100 L/min: 2.58 cm H2O</p> <p>The mask is labeled for use in the pressure range 4- 20 cm H2O.</p> <p>Single patient reuse cleaning has been validated for up to 1 year's use.</p> <p>Efficacy of high level disinfection/sterilization and mechanical integrity post disinfection are validated to set performance criteria.</p> <p>Compatible with ResMed CPAP and Bi-Level flow generators with "SWIFT" or "MIRAGE" settings.</p> <p>Transportation and storage environmental tolerances are validated to set performance criteria.</p>	<p>The flow and through impedance of the new device is substantially equivalent to the predicate device.</p> <p>The single patient reuse and multi patient reuse performance of the new device is substantially equivalent to the predicate device.</p> <p>The compatibility of the new device with ResMed flow generators is substantially equivalent to the predicate device.</p>

**Comparison of the new Swift FX to the predicate Ultra Mirage II (K050359)**

	New Device : Swift FX	Predicate Device: Ultra Mirage II (K050359)	Comparison
<p><i>Performance Pressure/Flow</i></p> <p><b>SUBSTANTIALLY EQUIVALENT</b></p>	<p>(b)(4)</p>	<p>The mask is labeled for use in the pressure range 4- 20 cm H2O.</p> <p>Physical dead-space of the Ultra Mirage II Nasal Mask (Shallow Wide) is 125 ml.</p> <p>Functional dead space of the Ultra Mirage II Nasal Mask (Standard) @ 4cm H2O is 53 ml.</p>	<p>The pressure flow characteristics and effectiveness of the new device and the predicate are equivalent.</p> <p>The CO<sub>2</sub> performance (functional dead space) of the new device is substantially equivalent to the predicate device.</p>

## 13. Proposed Labelling

***User Manual*** The new Swift FX packaging includes a printed user manual. A draft copy of the proposed user manual is included in the following pages.

***Disinfection and Sterilization Guide*** The Swift FX has been labeled for single-patient re-use in the home environment and multi patient reuse in the institutional environment. The disinfection and sterilization guide is intended for professional users and will be made available via ResMed web site when the product is released to the market. (ref: Section 502(f) of the Federal Food, Drug, and Cosmetic Act ) The User Manual identifies the URL of the ResMed web site where the disinfection and sterilization guide can be found.

A draft copy of the proposed disinfection and sterilization guide is included in the following pages.

***Promotional Material*** No promotional material has been released at the time of this 510(k) submission. The indication statement in any future promotional literature will be the same as that provided in the Indications For Use Statement made in this submission. No additional claims will be made. Any descriptive content in the promotional material will be consistent with this submission.

# *RESMED*

## **Swift™ FX**

NASAL PILLOWS SYSTEM

## **User Guide**

English

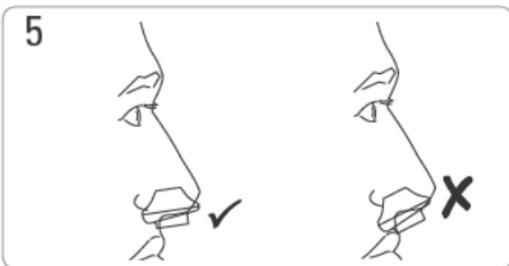
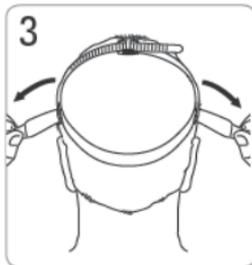


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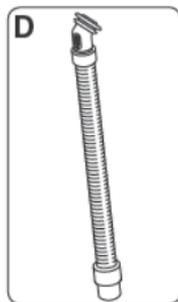
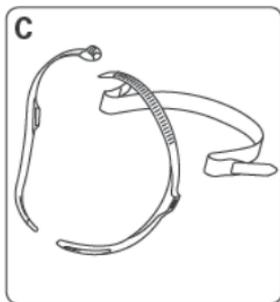
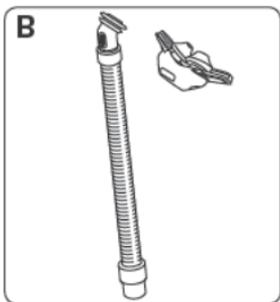
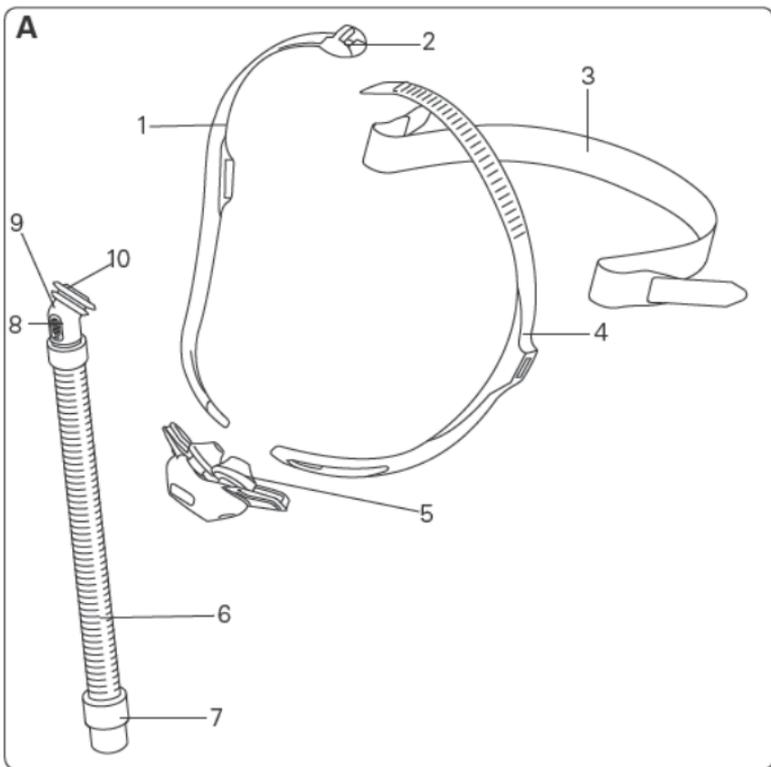
## Swift™ FX

Rx Only

### Fitting



# Swift FX

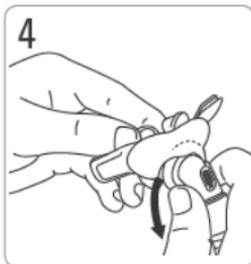
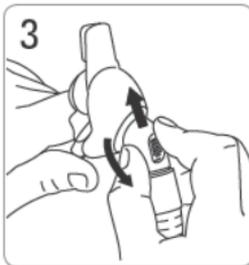
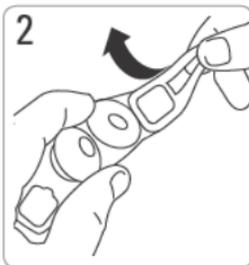


**Mask components**

Item	Description	Part number
1	Headgear right	-
2	Top buckle	-
3	Back strap	-
4	Headgear left	-
5	Pillows	61521 (S) 61522 (M) 61523 (L)
6	Short tube	-
7	Swivel	-
8	Vent	-
9	Elbow	-
10	Swivel ring	-
A	Complete system	61500
B	Pillows system	61510 (XS) 61511 (S) 61512 (M) 61513 (L)
C	Headgear assembly	61529
D	Short tube assembly	61528 (1) 61527 (10)
<b>Also available</b>		
	Pillows	61520 (XS)

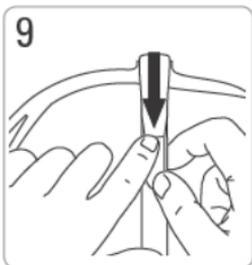
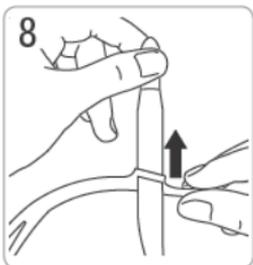
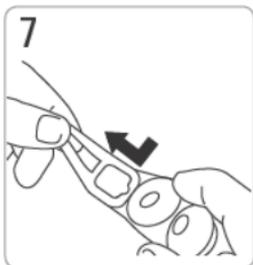
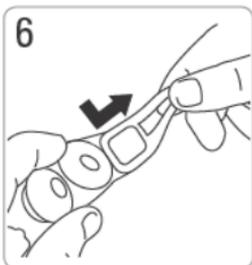
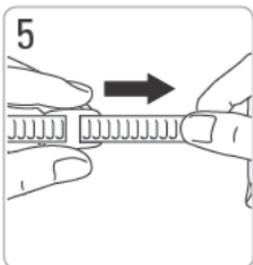
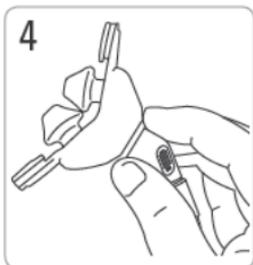
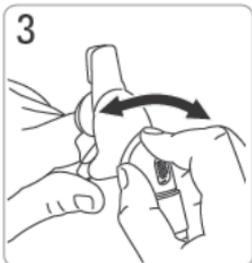
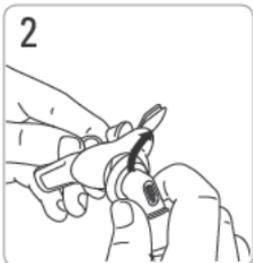
XS Extra Small, S Small, M Medium, L Large

## Disassembly



## Reassembly

English



English

## Swift™ FX

### NASAL PILLOWS SYSTEM

Thank you for choosing the Swift FX.

### Intended use

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

### Using your mask

When using your mask with ResMed CPAP or bilevel devices that have mask setting options, refer to the Technical specifications section in this user guide for mask selection options.

For a full list of compatible devices for this mask, see the Mask/Device Compatibility List on [www.resmed.com](http://www.resmed.com) on the **Products** page under **Service & Support**. If you do not have internet access, please contact your ResMed representative.

#### Notes:

- *This mask is not compatible for use with ResMed AutoSet CS™ 2 and VPAP™ Adapt SV devices.*
- *SmartStop may not operate effectively when using this mask with some CPAP or bilevel devices that have this feature.*
- *If you experience nasal dryness or irritation, use of a humidifier is recommended.*

**WARNING**

- The vent holes must be kept clear.
- The mask should not be used unless the CPAP system is turned on and operating properly.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the CPAP or bilevel device is not operating, so that unused oxygen does not accumulate within the CPAP or bilevel device enclosure and create a risk of fire.
- At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate.
- The technical specifications of the mask are provided for your clinician to check that they are compatible with the CPAP or bilevel device. If used outside specification or if used with incompatible devices, the seal and comfort of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect the CPAP or bilevel device function.
- Discontinue using this mask if you have ANY adverse reaction to the use of the mask, and consult your physician or sleep therapist.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.
- As with all masks, some rebreathing may occur at low CPAP pressures.
- Refer to your CPAP or bilevel device manual for details on settings and operational information.
- Remove all packaging before using the mask.

## Cleaning your mask in the home

Your mask and headgear should only be handwashed by gently rubbing in warm (approximately 86°F/30°C) water using mild soap. All components should be rinsed well with drinking quality water and allowed to air dry out of direct sunlight.

### Daily/After each use:

- To optimize the mask seal, facial oils should be removed from the cushion after use.
- Handwash the separated mask components (excluding headgear).
- If the vent requires cleaning use a soft bristle brush.

### Weekly:

- Handwash the headgear. It may be washed without being disassembled.



### WARNING

Do not use aromatic-based solutions or scented oils (eg, eucalyptus or essential oils), bleach, alcohol or products that smell strongly (eg, citrus) to clean any of the mask components. Residual vapours from these solutions can be inhaled if not rinsed thoroughly. They may also damage the mask, causing cracks.



### CAUTION

- If any visible deterioration of a system component is apparent (cracking, crazing, tears or cushion damage), the component should be discarded and replaced.
- Avoid connecting flexible PVC products (eg, PVC tubing) directly to any part of the mask. Flexible PVC contains elements that can be detrimental to the materials of the mask, and may cause the components to crack or break.

## Reprocessing the mask between patients

This mask should be reprocessed when used between patients. Cleaning, disinfection and sterilization instructions are available from the ResMed website, [www.resmed.com/masks/sterilization/americas](http://www.resmed.com/masks/sterilization/americas). If you do not have internet access, please contact your ResMed representative.

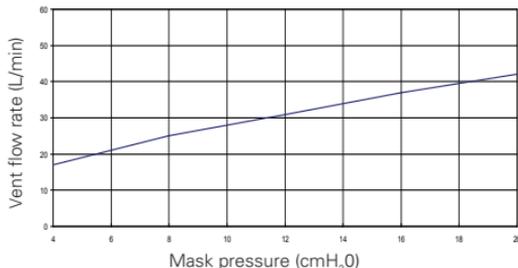
## Troubleshooting

Problem / possible cause	Solution
<b>Pillows won't seal properly, are uncomfortable or cause red marks</b>	
Pillows may have been fitted incorrectly, adjusted incorrectly or the headgear is too tight.	Check that the ResMed logo on top of the pillows is facing outwards. Carefully follow the fitting instructions. Readjust the headgear to ensure it is not over tightened.
Inner wall position of one or both pillows is incorrect.	Squeeze pillow sides to release inner wall. The correct position is shown in the reassembly instructions.
Pillows are the wrong size.	Talk to your clinician.
Pillows may be dirty.	Clean pillows according to the instructions.
<b>Mask is too noisy</b>	
System is assembled incorrectly.	Disassemble the mask, then reassemble according to the instructions.
System is leaking air.	Refit or reposition you mask. Adjust your headgear. Check your mask is assembled correctly.
Vent is blocked or partially blocked.	If the vent requires cleaning, use a soft bristle brush.

## Technical specifications

### Pressure-flow curve

The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations, the vent flow rate may vary.



Pressure (cm H <sub>2</sub> O)	Flow (L/min)
4	17
8	25
12	31
16	37
20	42

### Dead space information

Physical dead space is the empty volume of the mask to the end of the swivel. Using the large cushions it is 103 mL.

### Therapy pressure

4 to 20 cm H<sub>2</sub>O

### Resistance

Drop in pressure measured (nominal)  
at 50 L/min: 0.5 cm H<sub>2</sub>O  
at 100 L/min: 1.8 cm H<sub>2</sub>O

### Environmental conditions

Operating temperature: +41°F to 104°F (+5°C to +40°C)  
Operating humidity: 15% to 95% relative humidity non-condensing  
Storage and transport: -4°F to 140°F (-20°C to +60°C)  
Storage and transport humidity: up to 95% relative humidity non-condensing

### Gross dimensions

XS, S, M, L: 16.53" (H) 3.66" (W) 1.77" (D)  
(420 mm (H) x 93 mm (W) x 45mm (D))  
Mask fully assembled – no headgear

### Mask setting options

Select 'SWIFT', otherwise select 'MIRAGE' as the mask option.

### Notes:

- The mask system does not contain latex, PVC or DEHP materials.
- The manufacturer reserves the right to change these specifications without notice.

## Storage

Ensure that the mask is thoroughly clean and dry before storing it for any length of time. Store the mask in a dry place out of direct sunlight.

## Disposal

This mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

## Symbols

 Caution, consult accompanying documents;  Lot number;  Part number;  Temperature limitation;  Humidity limitation;  Does not contain latex;  Manufacturer;  Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device;  Keep away from rain;  This way up;  Fragile, handle with care.

## Limited warranty

ResMed Limited (hereafter 'ResMed') warrants that your ResMed mask system (including mask frame, cushion, headgear and tubing) ("Product") shall be free from defects in material and workmanship for a period of ninety (90) days. This warranty is only available to the initial consumer. It is not transferable.

If the product fails under conditions of normal use, ResMed will repair or replace, at its option, the defective product or any of its components.

This Limited Warranty does not cover:

- any damage caused as a result of improper use, abuse, modification or alteration of the product,
- repairs carried out by any service organization that has not been expressly authorized by ResMed to perform such repairs;
- any damage or contamination due to cigarette, pipe, cigar or other smoke.

Warranty is void on product sold, or resold, outside the region of original purchase.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

ResMed shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from region to region.

For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

**Manufacturer:**

ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia.

**Distributed by:**

ResMed Corp 14040 Danielson Street Poway CA 92064-6857 USA. ResMed (UK) Ltd 96 Milton Park Abingdon Oxfordshire OX14 4RY UK.

See [www.resmed.com](http://www.resmed.com) for other ResMed locations worldwide.

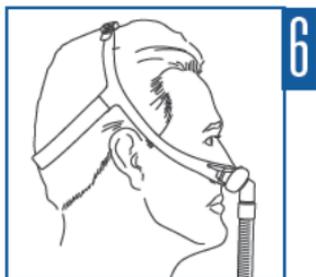
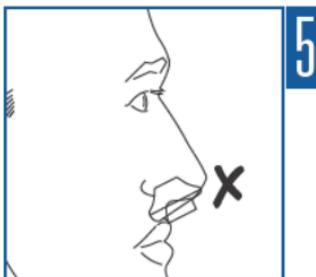
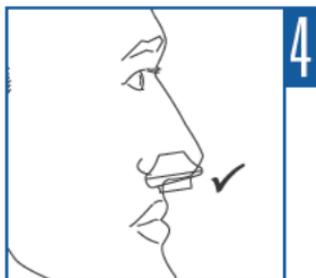
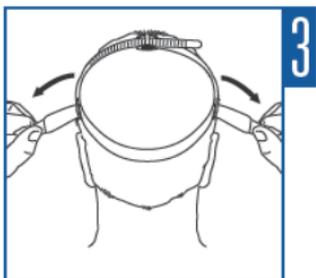
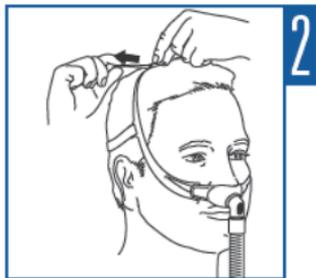
**Swift FX**

Protected by patents: AU 785376, HK 1057714, EP 1314445, EP 1582230, US 6581594, US 6823865, US 7159587. Other patents pending.

Protected by design registration: US D562976. Others designs pending.

Swift is a trademark of ResMed Ltd and Swift is registered in U.S. Patent and Trademark Office.

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SWIFT FX
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## Clinical Use Only

# **RESMED**

## **ResMed Masks**

### **Disinfection and Sterilization Guide**

**Mirage Activa™**  
**Mirage Activa™ LT**  
**Mirage Kidsta™**  
**Mirage Micro™**  
**Mirage Vista™**  
**Ultra Mirage™ II**  
NASAL MASKS

**Ultra Mirage™**  
NON-VENTED NASAL MASKS

**Mirage Liberty™**  
**Mirage Quattro™**  
**Ultra Mirage™**  
FULL FACE MASKS  
**Ultra Mirage™**  
NON-VENTED FULL FACE MASK

**Swift™ LT**  
**Swift™ LT for Her**  
**Mirage Swift™ II**  
**Swift™ FX**  
NASAL PILLOWS SYSTEMS



## Clinical Use Only

### ResMed Masks – Disinfection and Sterilization Guide

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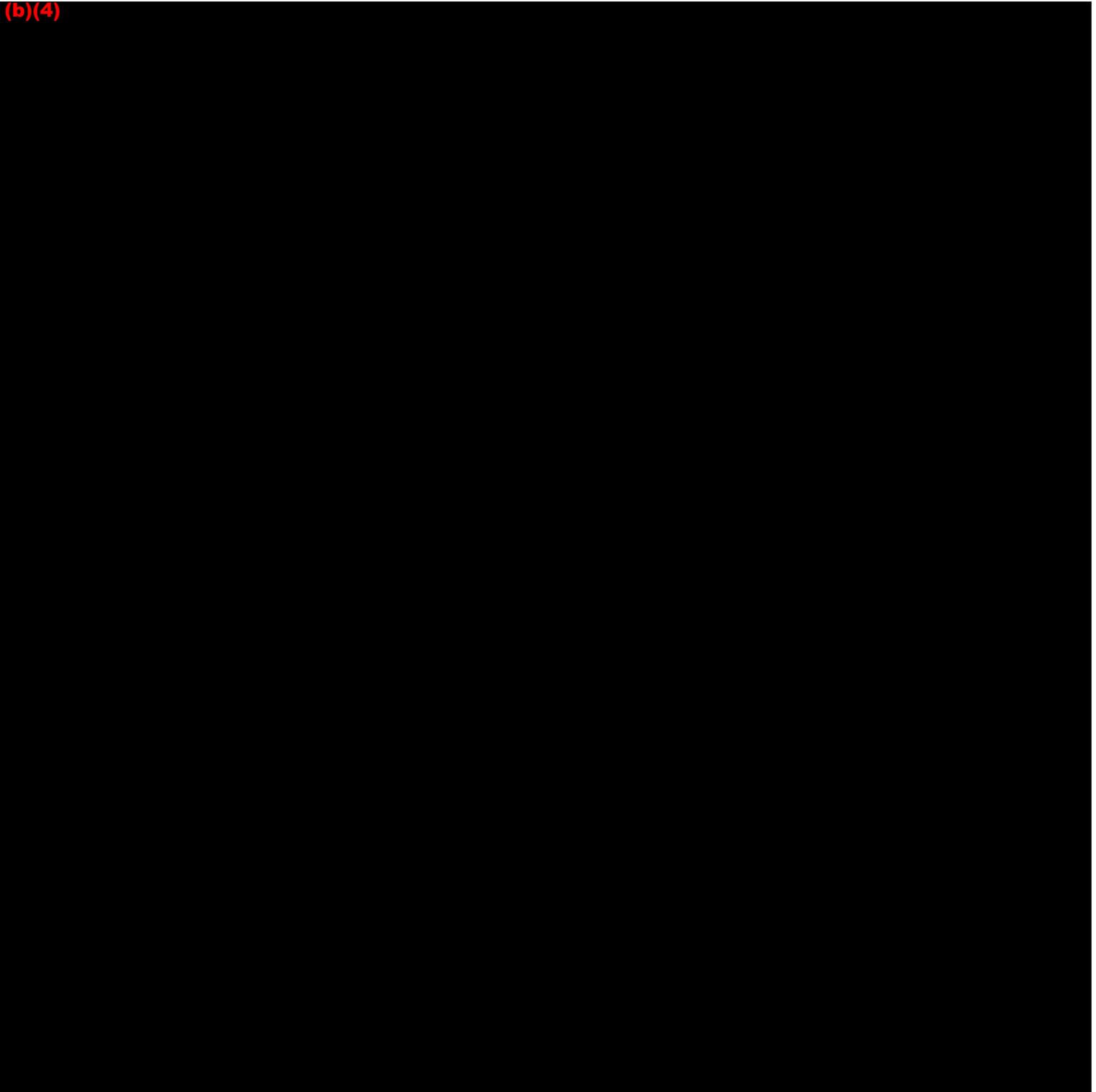
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<sup>1</sup> References to masks in this guide refer to ResMed masks *and* nasal pillows systems.

## Clinical Use Only

### 1. ResMed Masks

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## Clinical Use Only

### 2. ResMed Validated Procedures

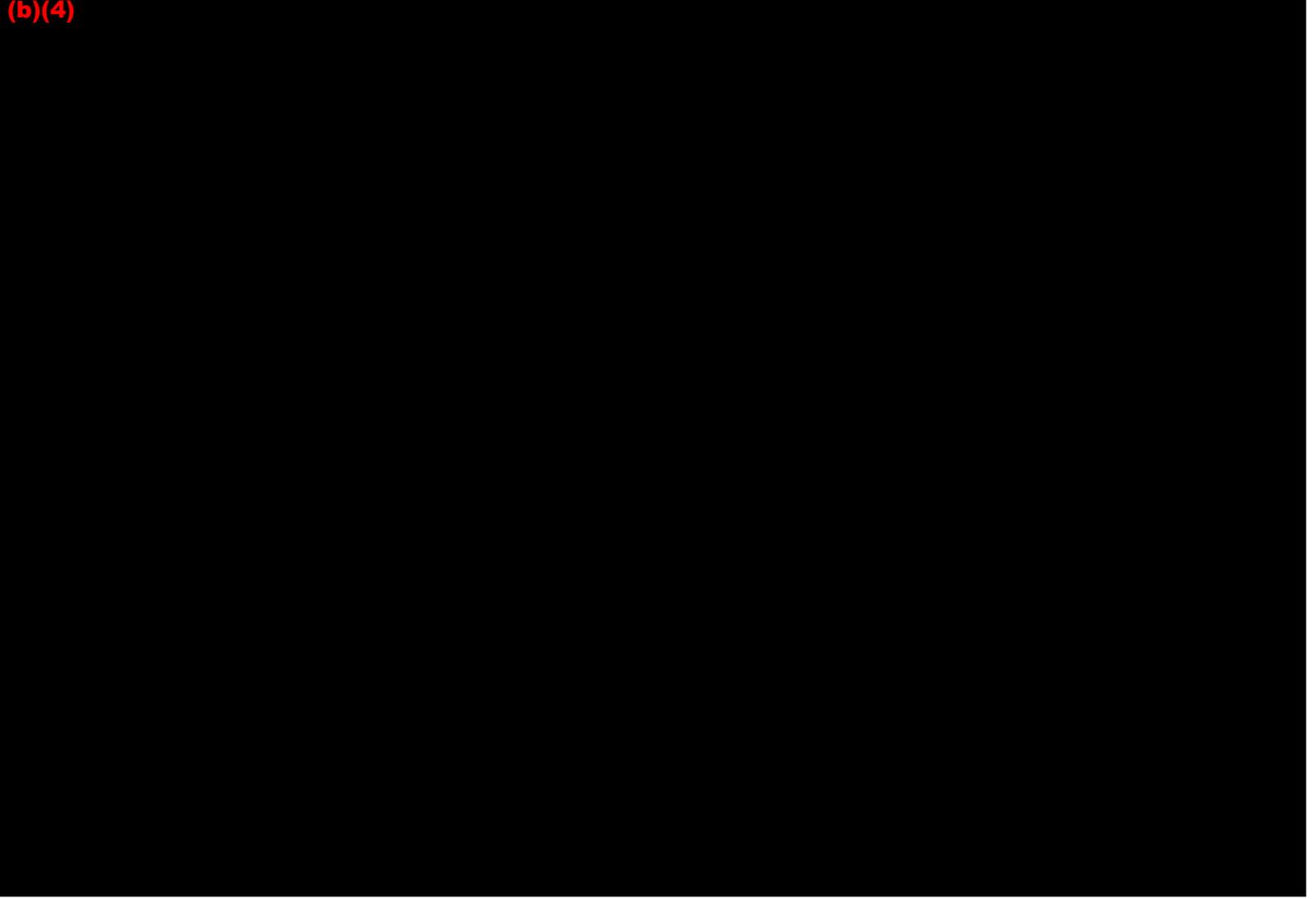
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## Clinical Use Only

Table 2.2: Option 2 (High-Level Chemical Disinfection)

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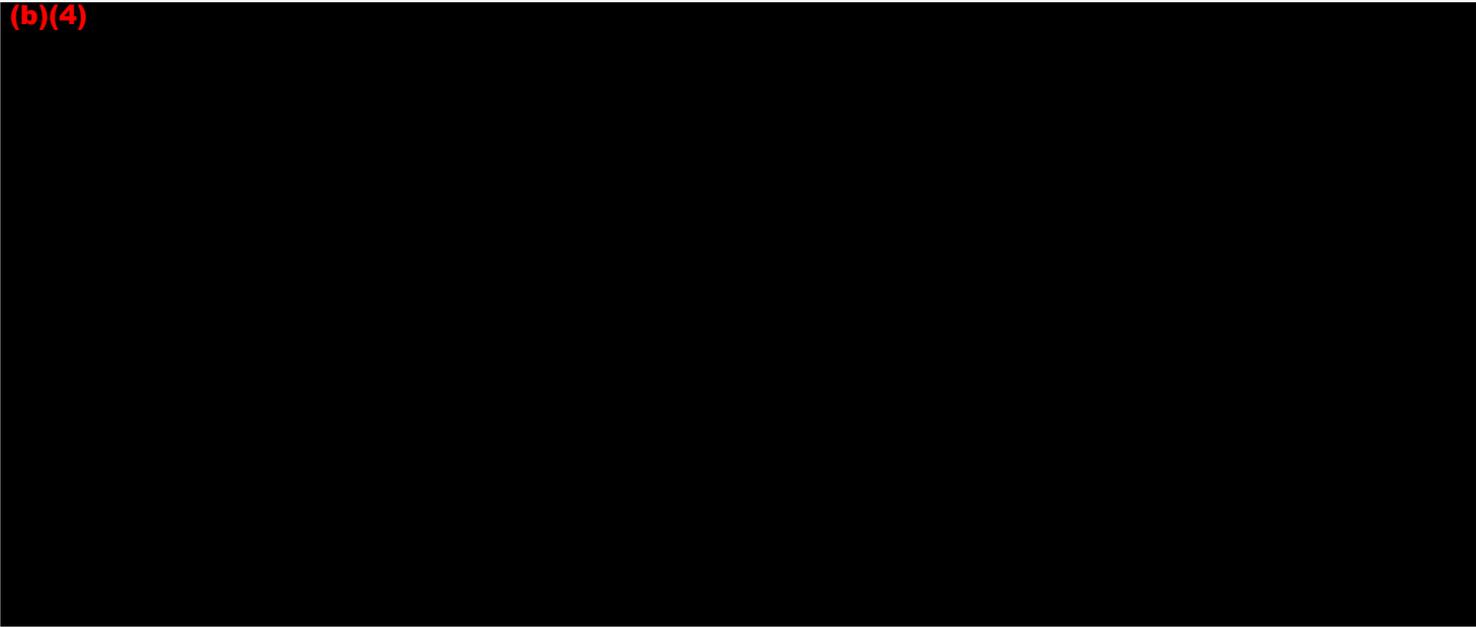
## Clinical Use Only

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## Clinical Use Only

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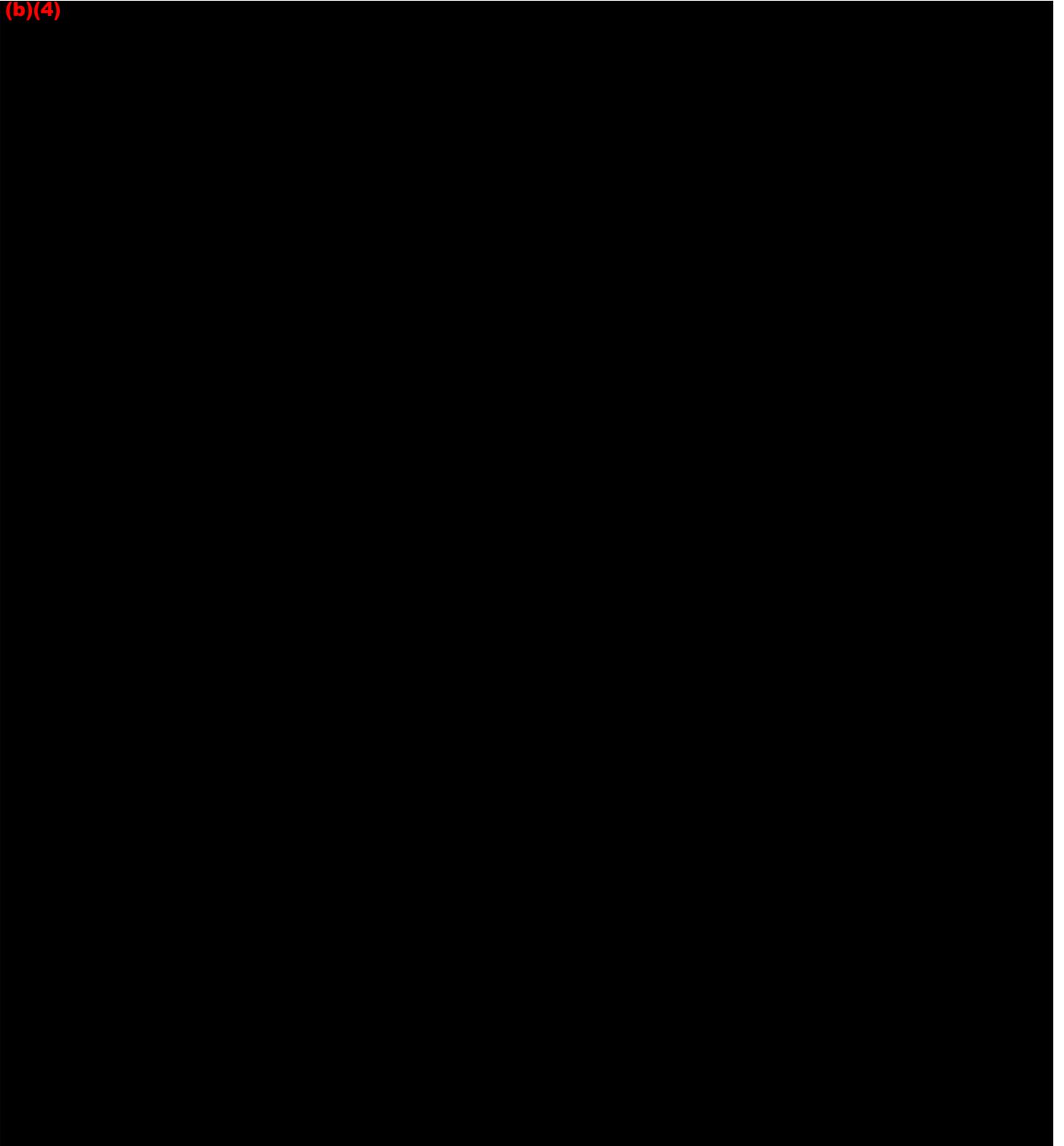
*RESMED*

Swift FX  
Traditional 510k

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## 14. Sterilization and Shelf Life

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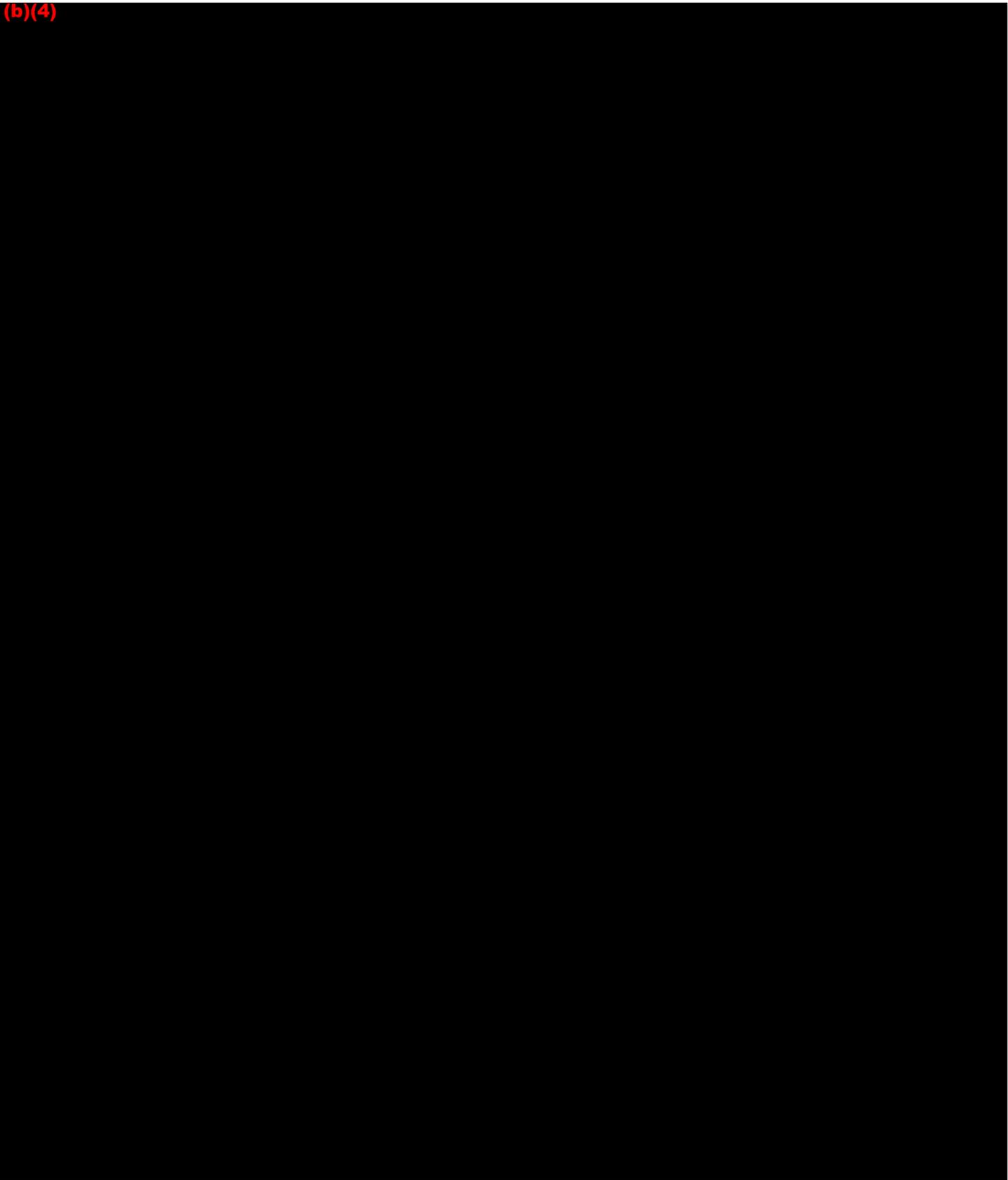
January 30, 2009

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Traditional 510k

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January 30, 2009

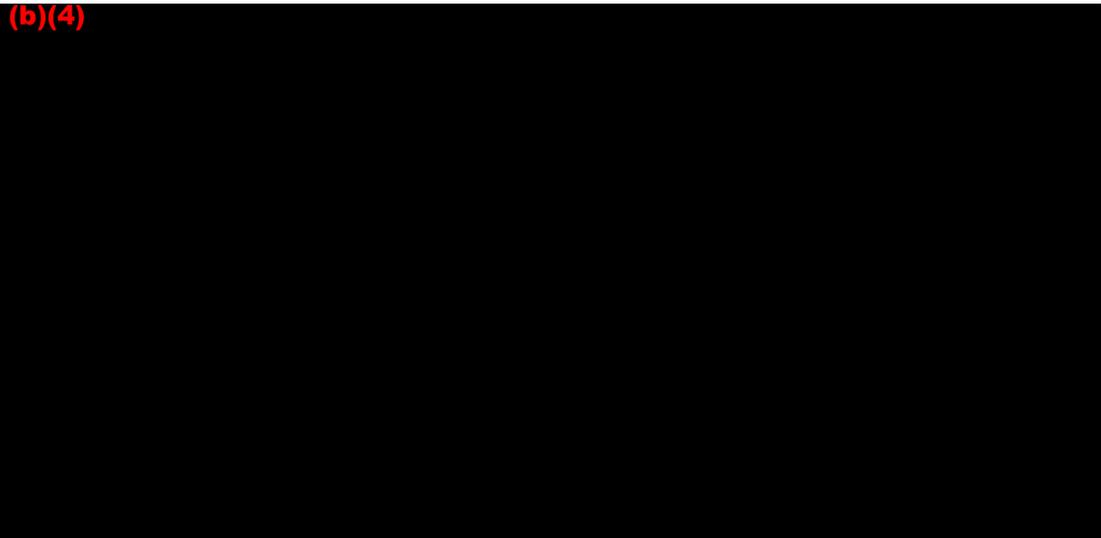
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Swift FX  
Traditional 510k

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Swift FX  
Traditional 510k

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## 15. Biocompatibility

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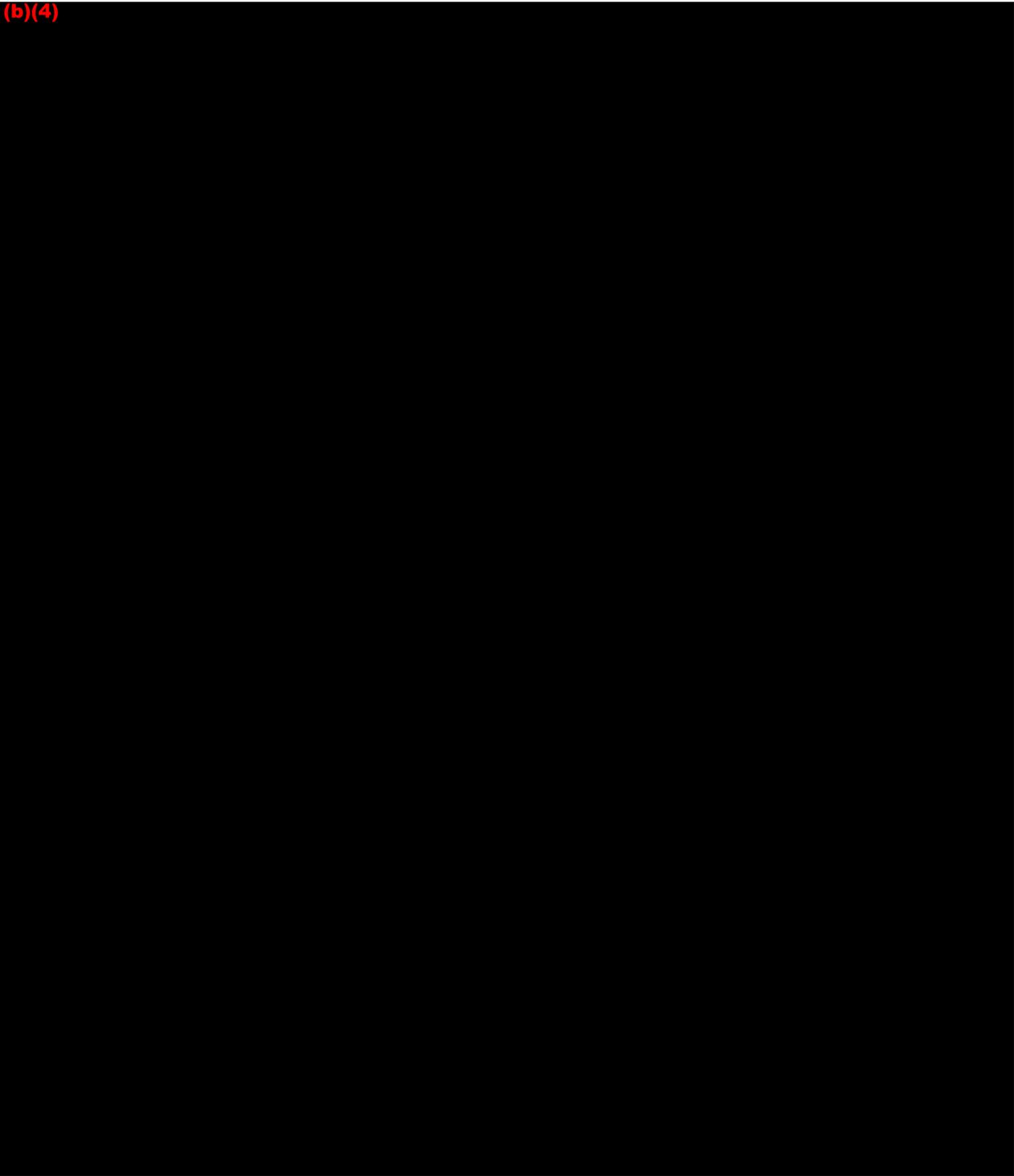


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Swift FX  
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January 30, 2009

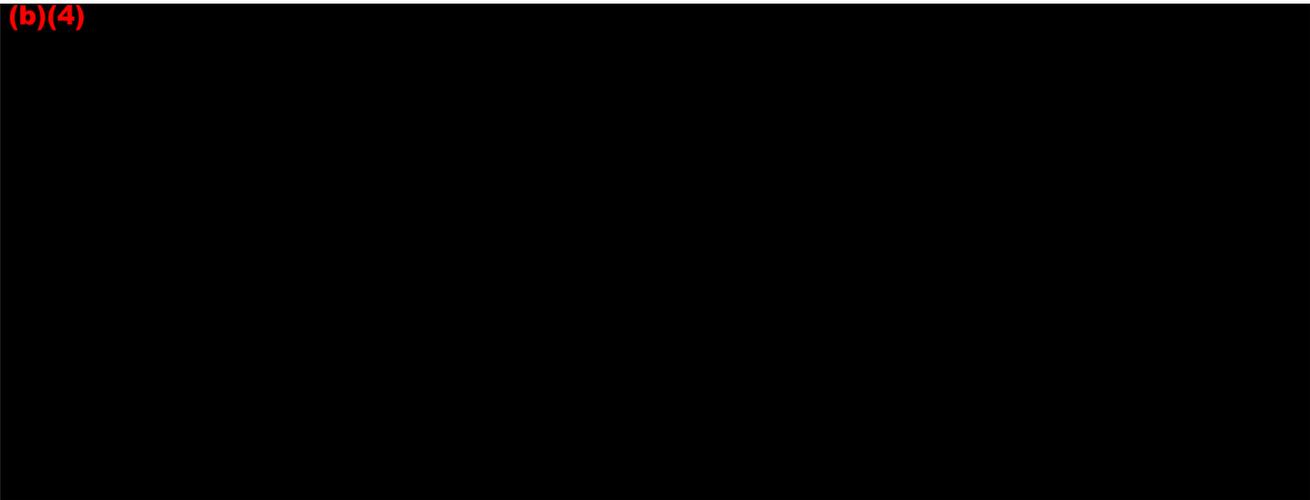
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Swift FX  
Traditional 510k

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*RESMED*

Swift FX  
Traditional 510k

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## **16. Software**

Swift FX does not include any software components.

*RESMED*

Swift FX  
Traditional 510k

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## **17. Electromagnetic Compatibility and Electrical Safety**

Swift FX does not include any electrical components.

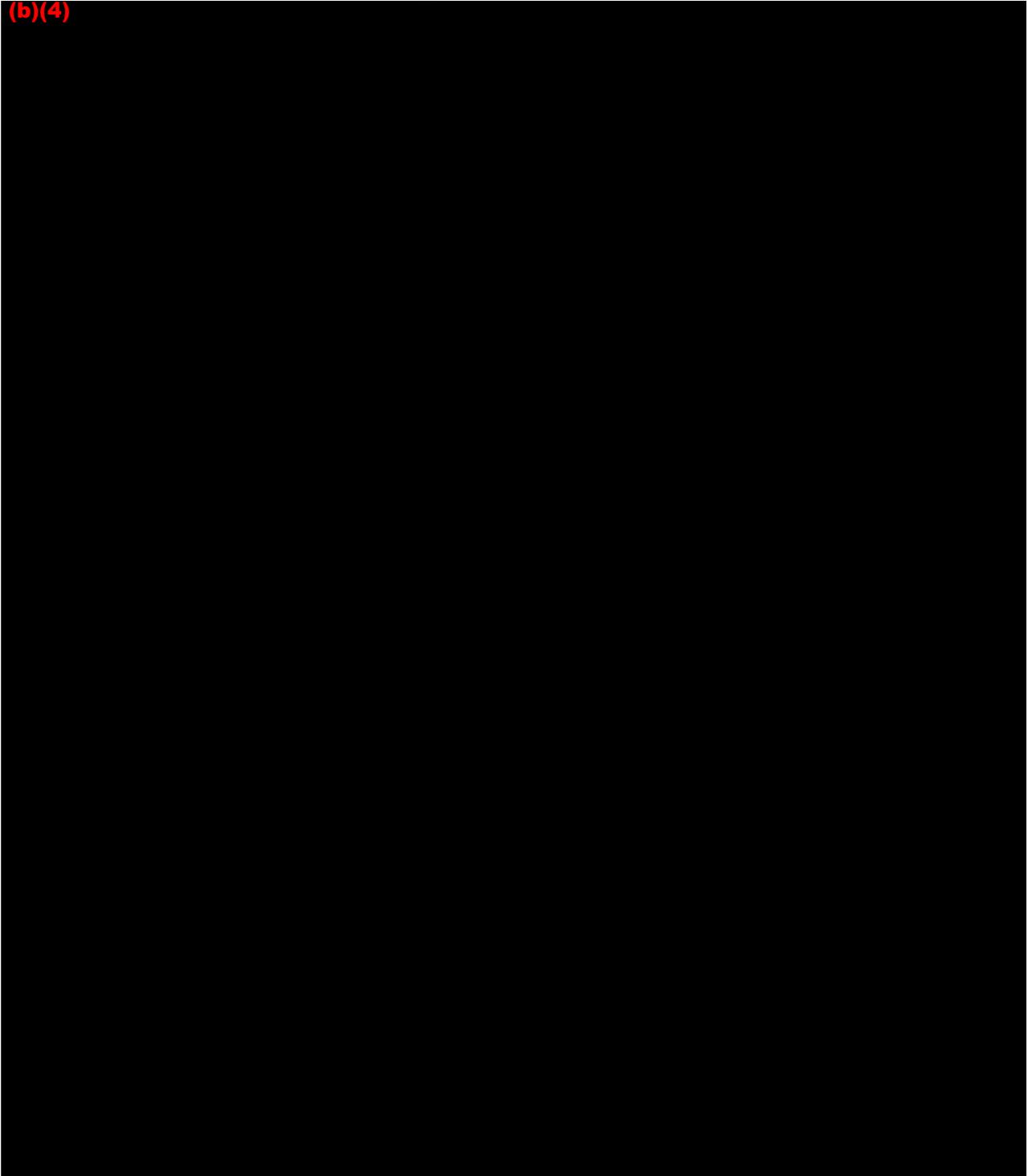
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Swift FX  
Traditional 510k

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## 18. Performance Testing – Bench

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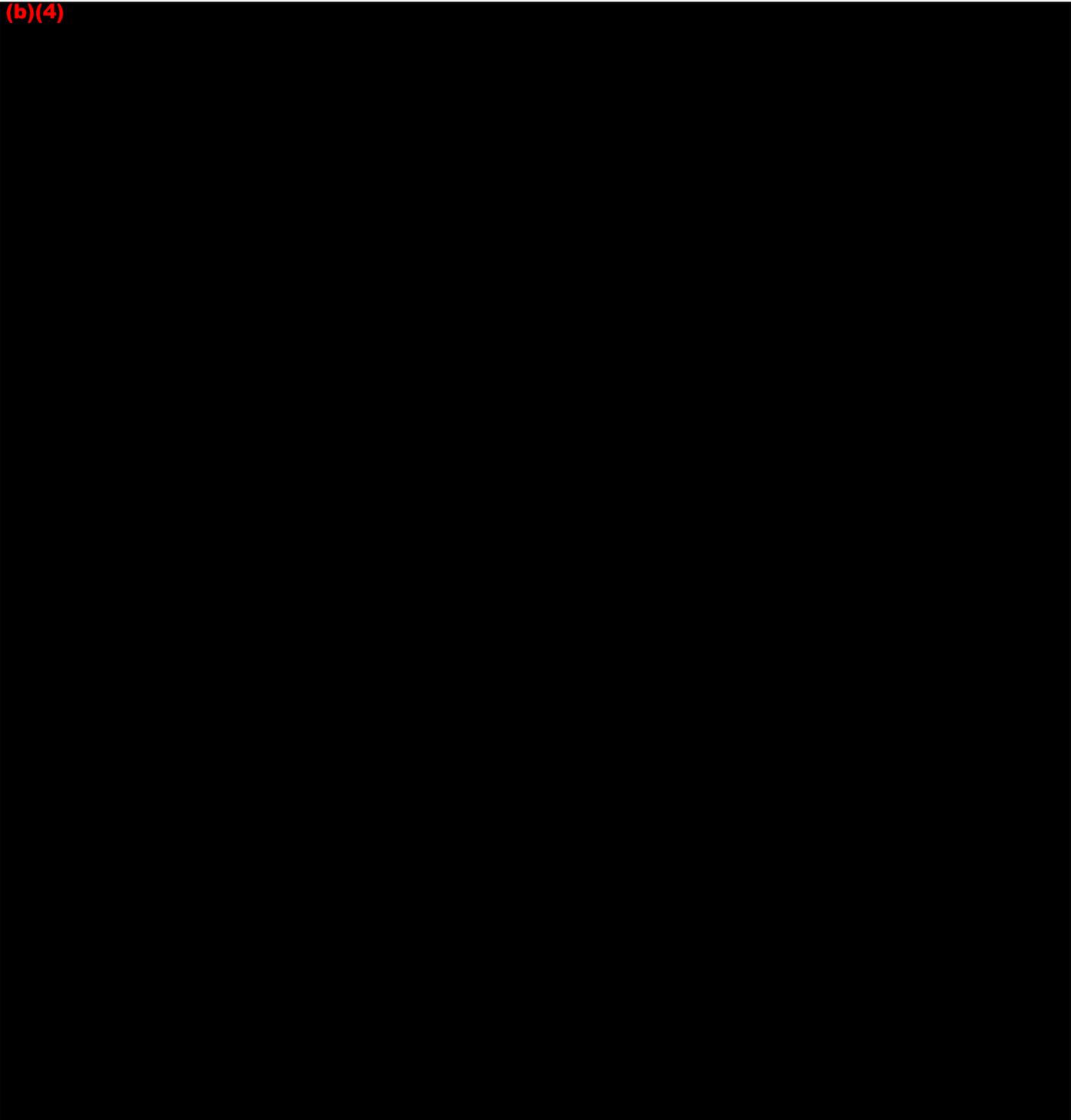


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Swift FX  
Traditional 510k

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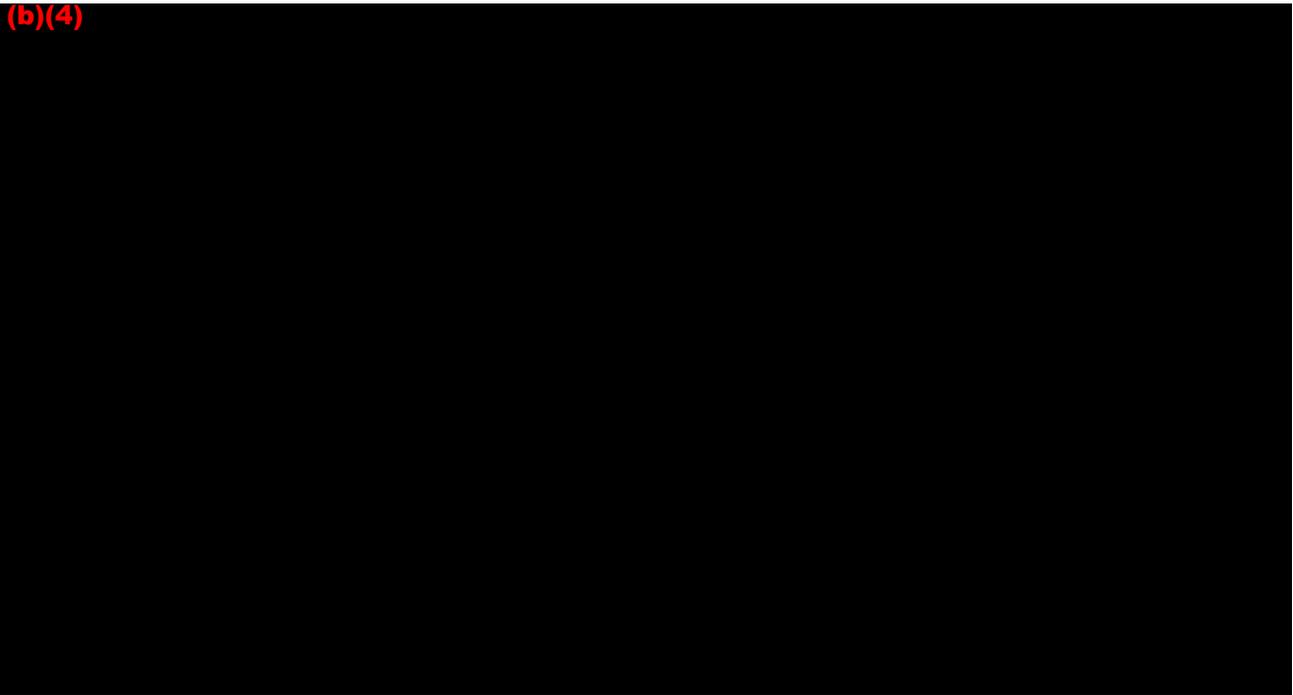


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Swift FX  
Traditional 510k

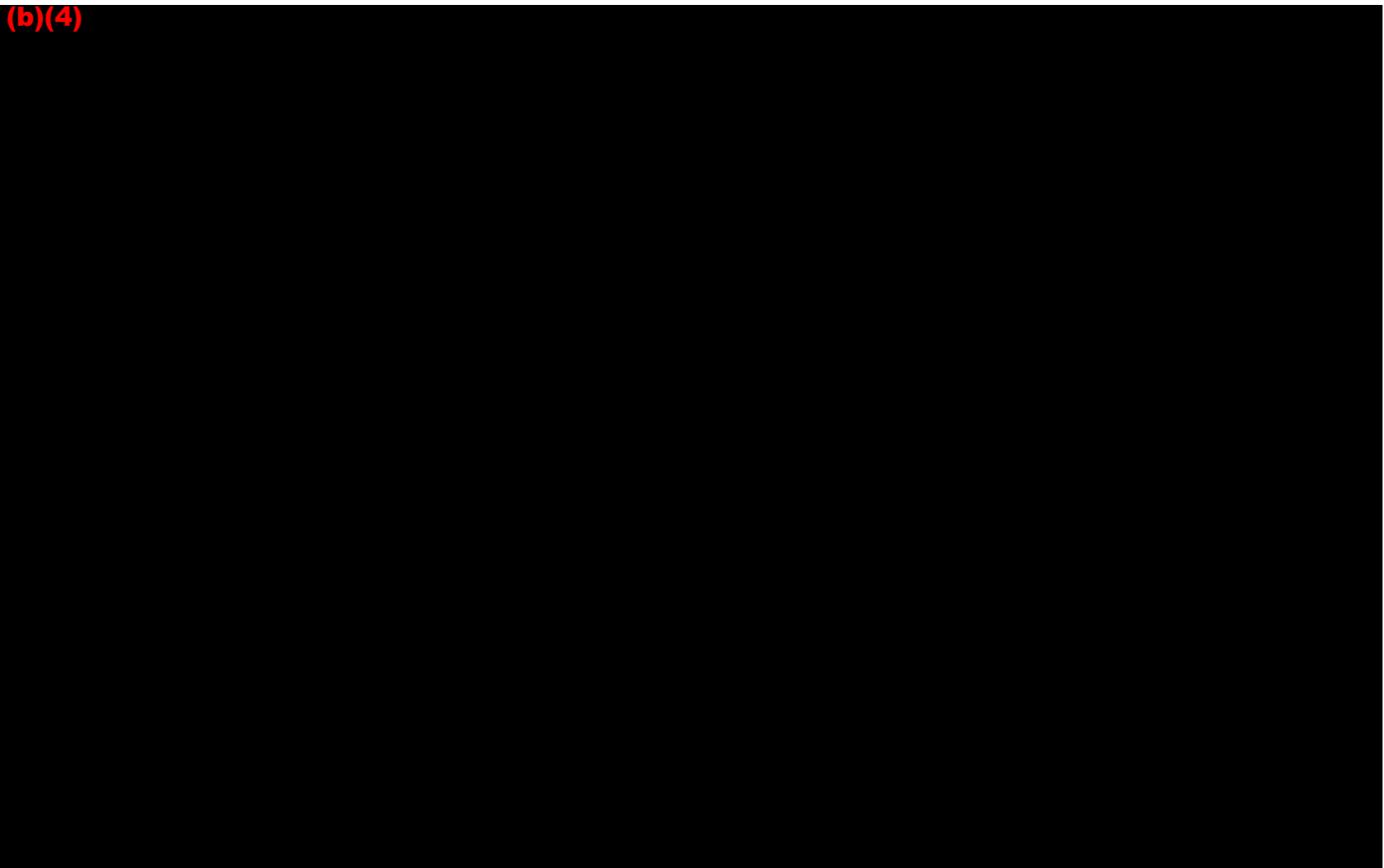
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**Mask Characteristics**

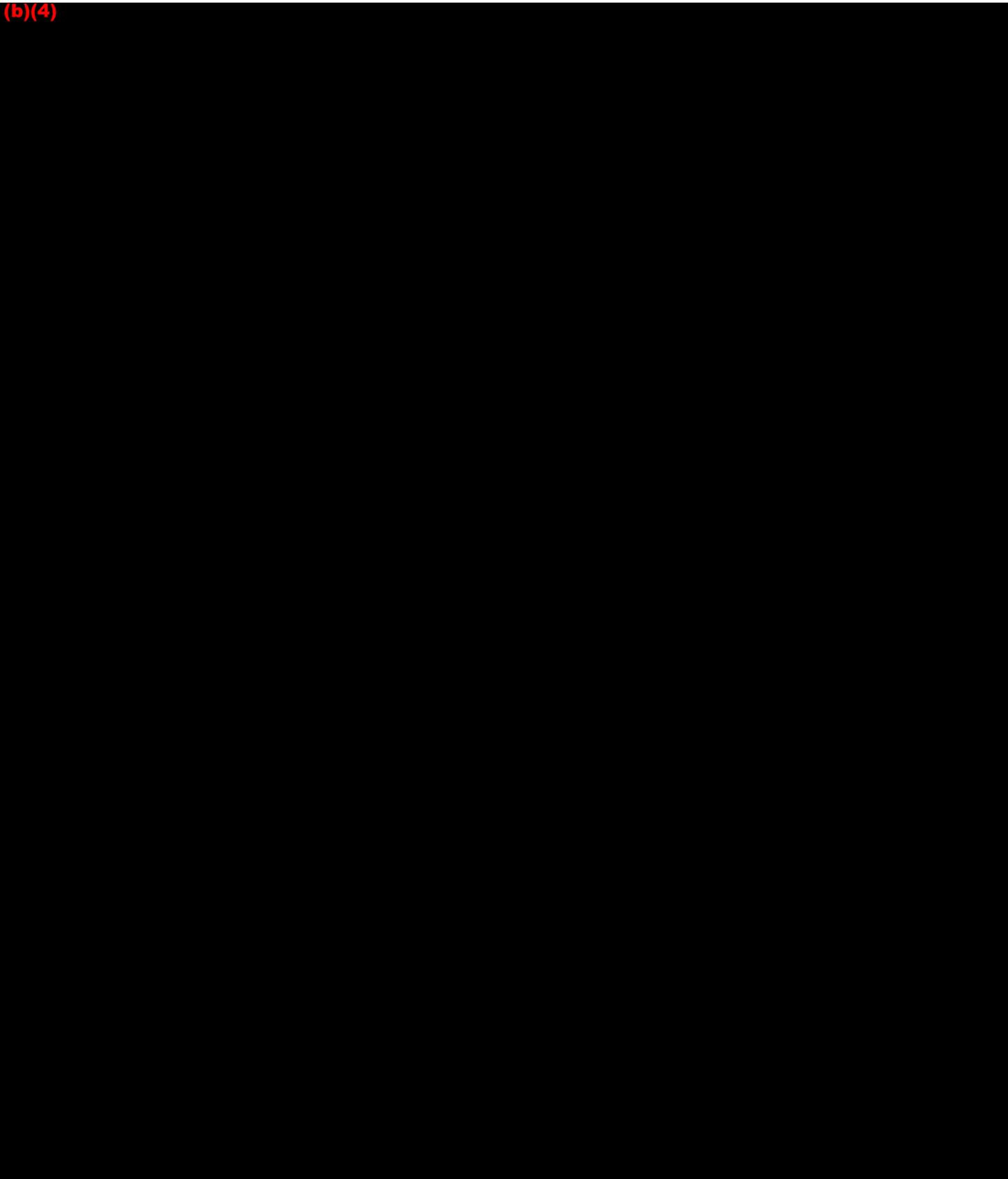
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Swift FX  
Traditional 510k

(b)(4)



January 30, 2009

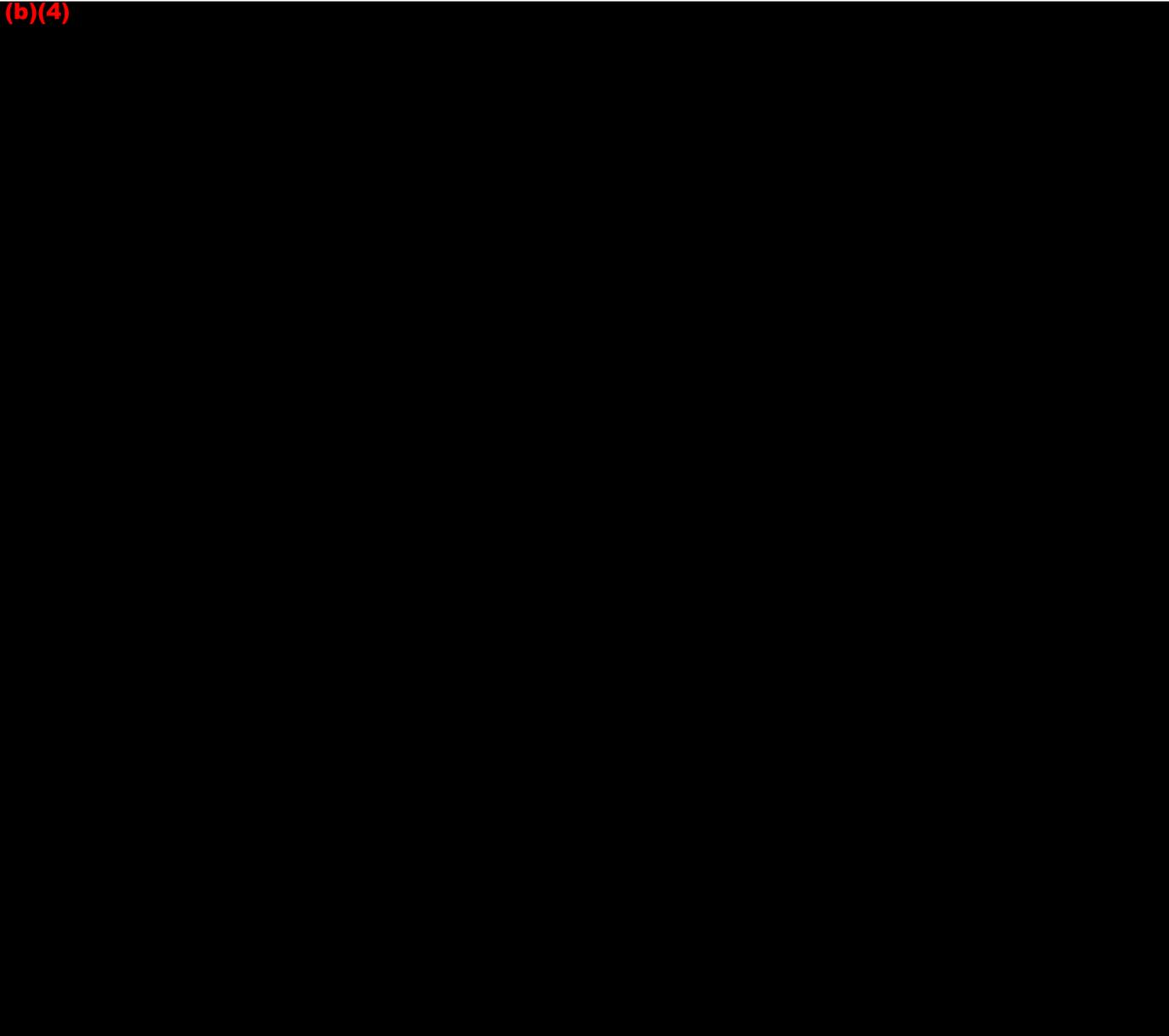
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*RESMED*

Swift FX  
Traditional 510k

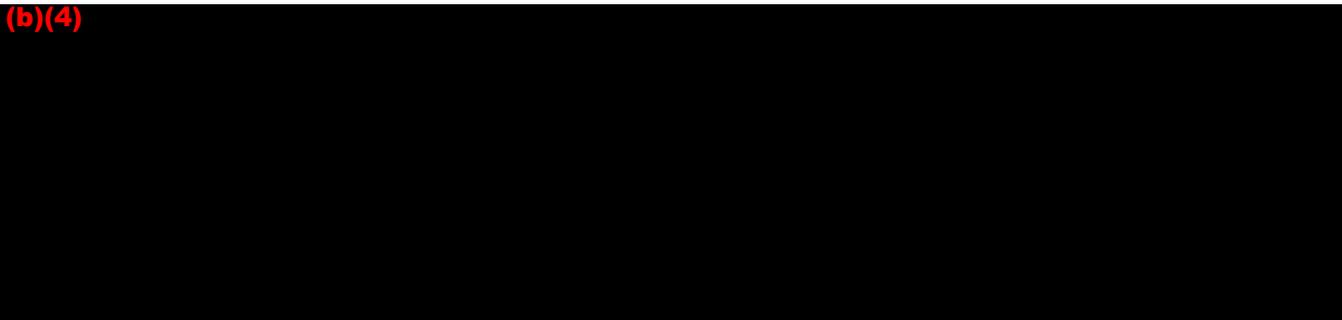
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**Assembly Integrity**

**(b)(4)**

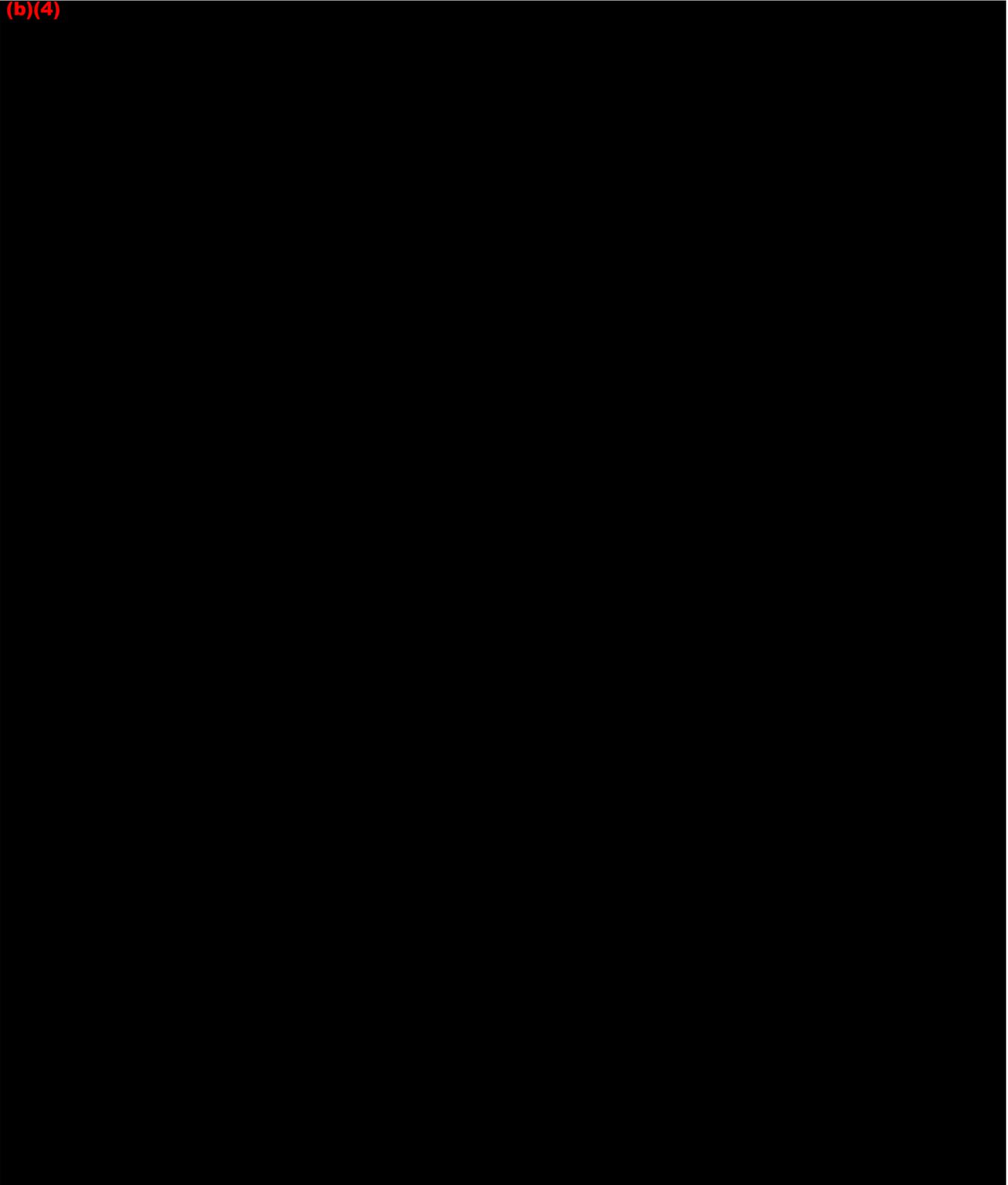


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Swift FX  
Traditional 510k

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January 30, 2009

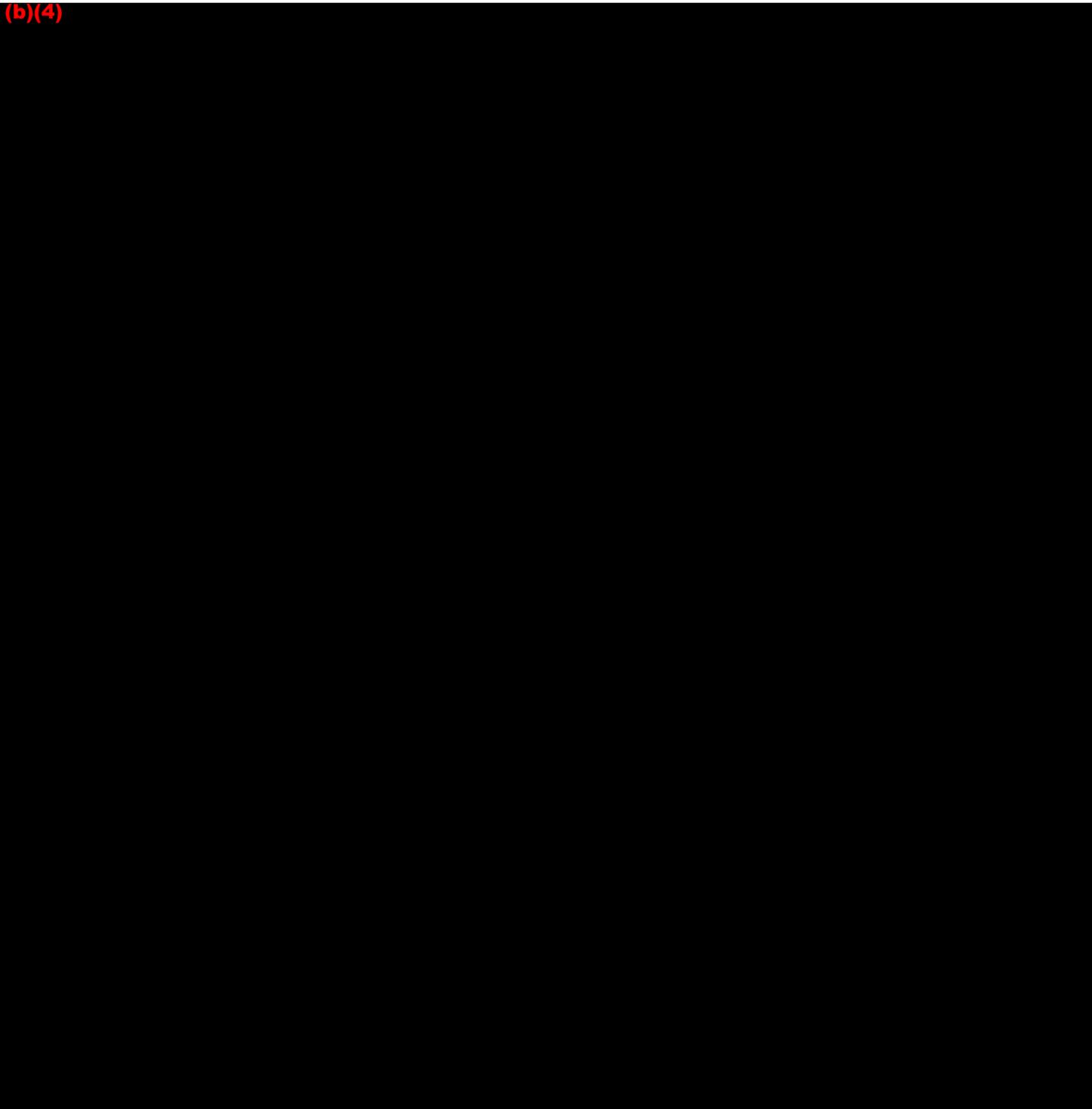
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Swift FX  
Traditional 510k

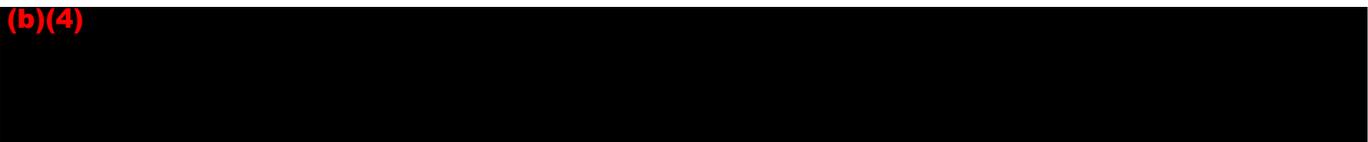
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**Transportation and Storage**

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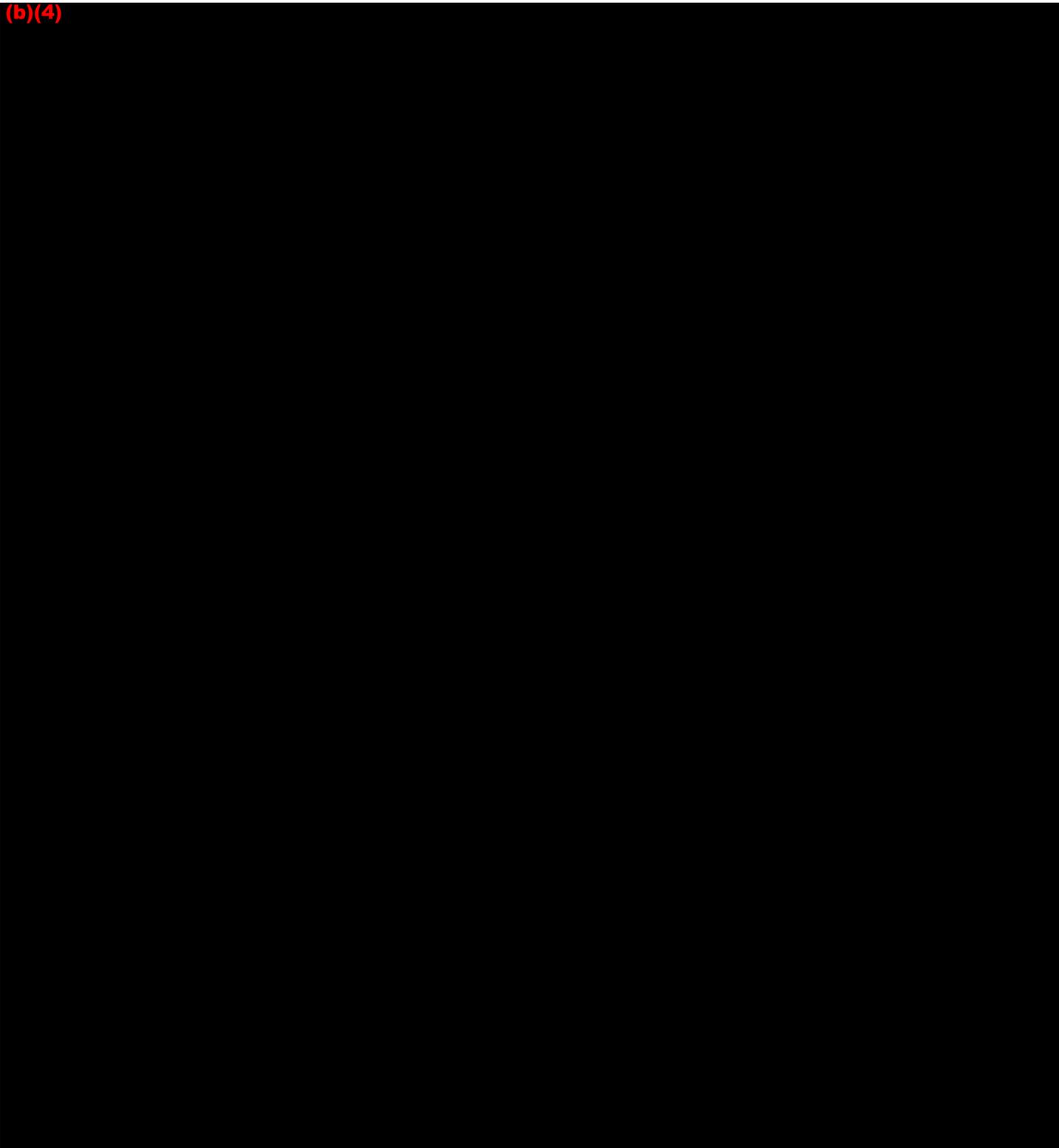
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Swift FX  
Traditional 510k

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*RESMED*

Swift FX  
Traditional 510k

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## **19. Performance Testing – Animal**

Swift FX validation did not require any performance testing involving animals.

*RESMED*

Swift FX  
Traditional 510k

---

## **20. Performance Testing – Clinical**

Swift FX validation did not require any clinical data.

Use of Nasal Masks with CPAP or Bilevel therapy and the use of nasal pillow systems to create a seal around the nostrils are proven technology and are well accepted by the medical community. Pre-clinical-data (bench testing) demonstrating safety and efficacy is sufficient substitute for clinical evidence.

*RESMED*

Swift FX  
Traditional 510k

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## **APPENDICES**

Appendix A	Bioburden Reduction Efficacy	80
Appendix B	Biocompatibility of Silicone LR 3043/40 & LR 3043/65	81-82

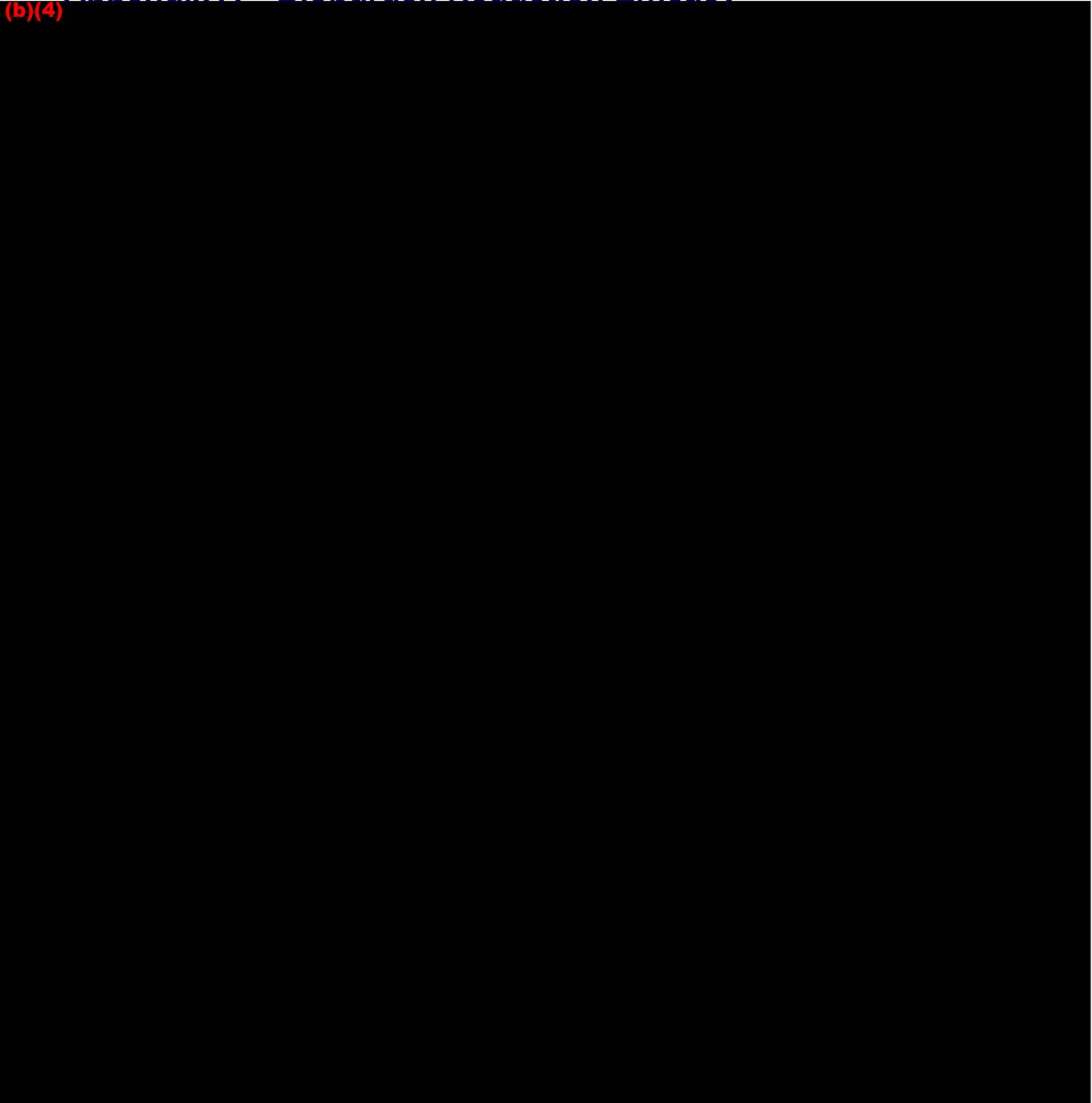
*RESMED*

Swift FX  
Traditional 510k

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## Appendix A – Bioburden Reduction Efficacy

(b)(4)



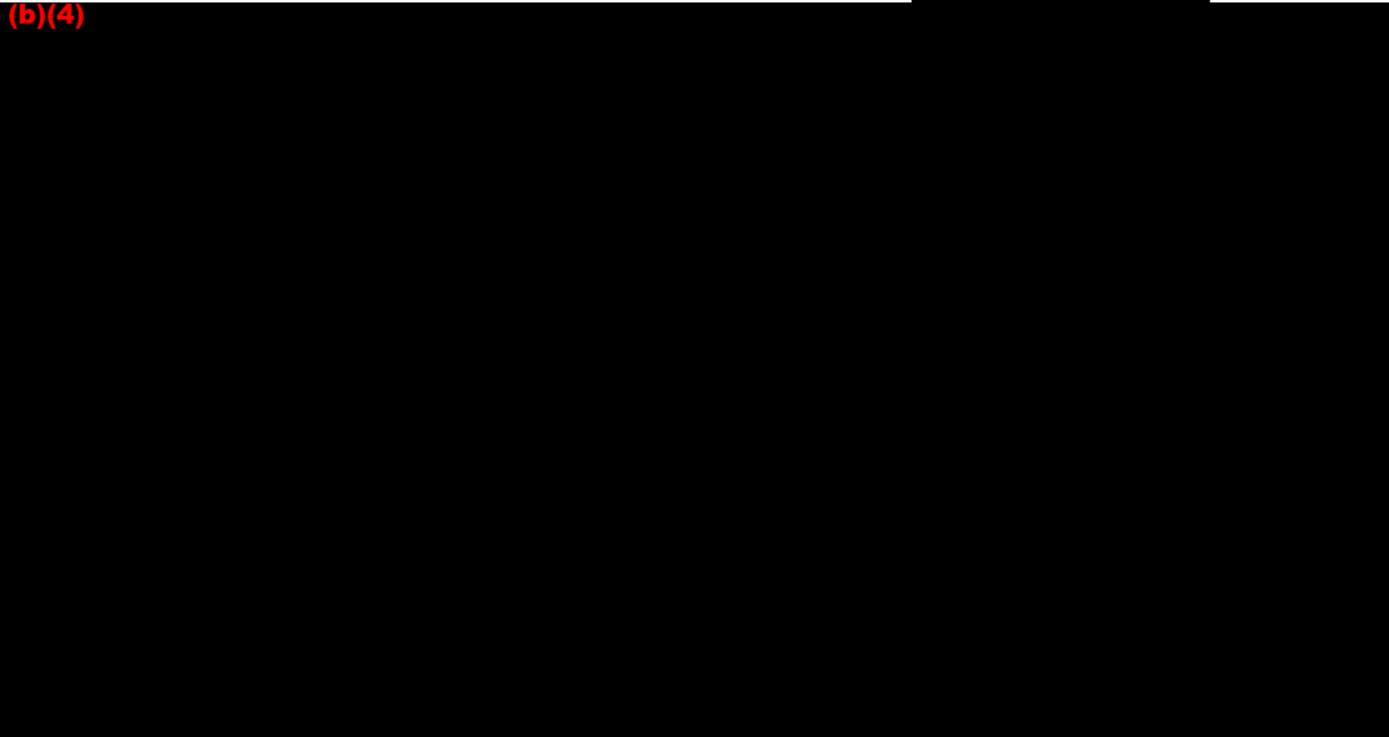
*RESMED*

Swift FX  
Traditional 510k

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**Appendix B – Biocompatibility of Silicone** (b)(4)

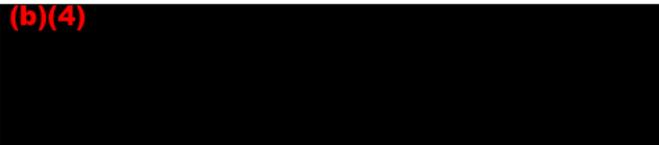
(b)(4)



*RESMED*

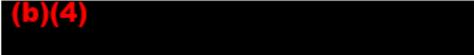
Swift FX  
Traditional 510k

(b)(4)

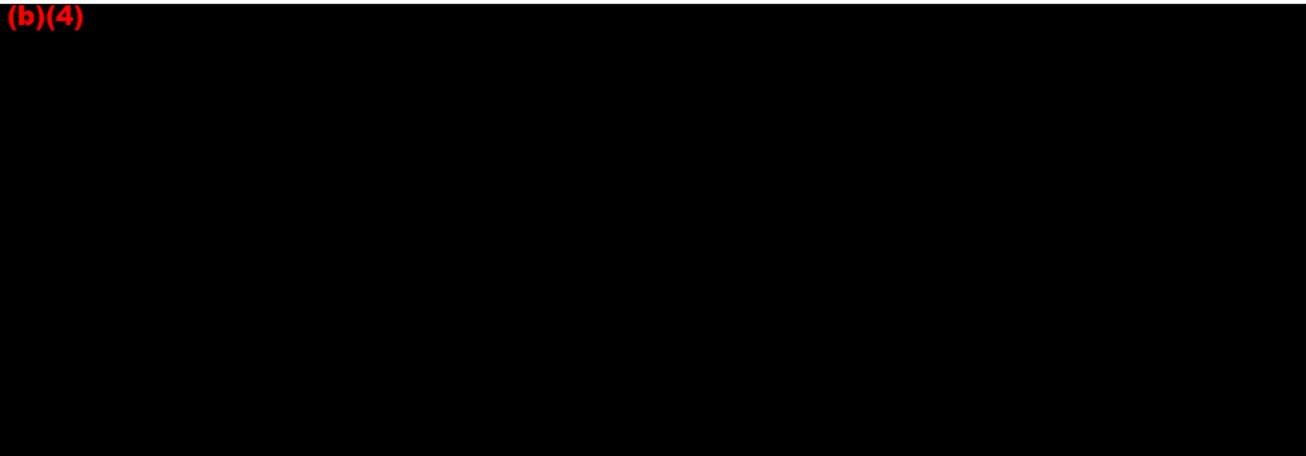


August 25, 2008

Confirmation of Biocompatibility (b)(4)



(b)(4)



Cathy Campbell  
Sr. Assistant Chemist  
Wacker Chemical Corp.  
3301 Sutton Road  
Adrian, MI 49221  
Phone: 517-264-8468  
FAX: 517-264-0959  
cathy.campbell@wacker.com

January 30, 2009

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**COVER SHEET MEMORANDUM**

From: Reviewer Name Charles M. Kerms  
Subject: 510(k) Number K090244  
To: The Record

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			✓
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓	
Nanotechnology		✓	✓

ev. 7/2/07

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, <a href="http://www.fda.gov/cdrh/osb/guidance/316.html">http://www.fda.gov/cdrh/osb/guidance/316.html</a> )	Contact OSB.		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC.		✓

Regulation Number 868.5905 Class\* II Product Code B2D  
 (\*If unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: [Signature] (Branch Chief) ARB/3 (Branch Code) 4/13/09 (Date)

Final Review: [Signature] (Division Director) 4/13/09 (Date)



## 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/Abbreviated**

**K090244**

Date: April 10, 2009

To: The Record

From: Charles M. Kerns, Regulatory Reviewer

Office: ODE

Division: DAGID/ARDB

510(k) Holder: ResMed Ltd.

Device Name: Swift FX

Contact: David D'Cruz

Phone: 858-746-2238

Fax: 858-746-2915

Email: [davidd@resmed.com](mailto:davidd@resmed.com)

**I. Purpose and Submission Summary**

The 510(k) holder would like to introduce the Swift FX into interstate commerce.

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (For Prescription use)	X		
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)?	X		
Are "cleaning" instructions included for the end user?			

The Swift FX is a nasal mask patient interface for use with continuous positive airway pressure (CPAP) or bi-level systems for the treatment of obstructive sleep apnea (OSA) or ventilatory

support in adult patients. It is for use in the pressure range of 4-20 cm H<sub>2</sub>O. The nasal mask has a mask cushion (nasal pillows) which acts as the chassis where other parts (elbow ring and headgear) connect. The mask cushion integrates the "dual wall" silicone cushion/nasal pillows which act as the patient interface.

The nasal pillows are available in four sizes extra small, small, medium and large, and are supported by short stalks and a trampoline-like base.

The mask cushion connects to an elbow tube via the elbow ring. The elbow ring is available in two colors, clear and grey. The elbow tube is connected to the elbow ring by way of an interference fit via a recess in the elbow. This fit is through a swivel adapter which creates a seal and allows the elbow to rotate 360 degrees. The elbow also has an integrated multi-hole vent array to provide CO<sub>2</sub> washout. The elbow is connected to the short tube assembly which attaches to the conventional 22 mm air delivery tubing.

The mask cushion also allows for the connection of the headgear assembly. The headgear assembly consists of a left and right strap and a back strap. The left and right straps engage each side of the frame and run up the sides of the face, where they connect with a buckle. The back strap feeds through slots on the right and left straps and is secured and adjusted using Velcro tabs.

#### IV. Indications for Use

The Indications for Use form is included in the submission in Section 4, it states:

The Swift FX channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Swift FX is:

- To be used by adult patients (>66lb/30kg) for whom positive airway pressure has been prescribed.
- Intended for single patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

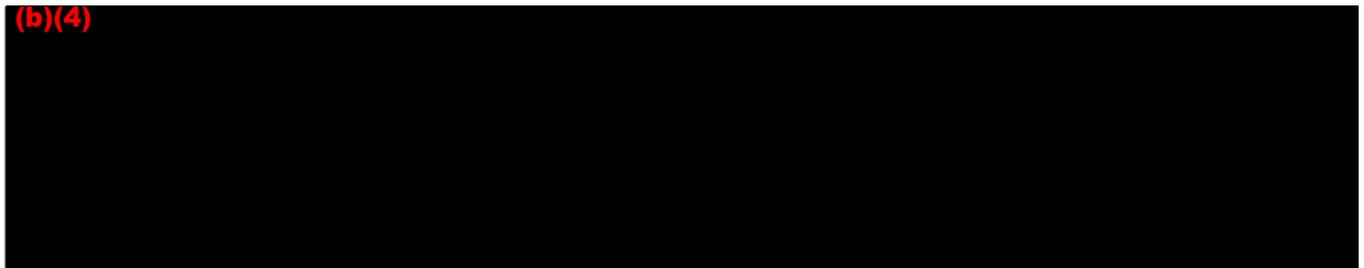
*Reviewer Comments: This is the identical IFU to the predicate device.*

#### V. Predicate Device Comparison

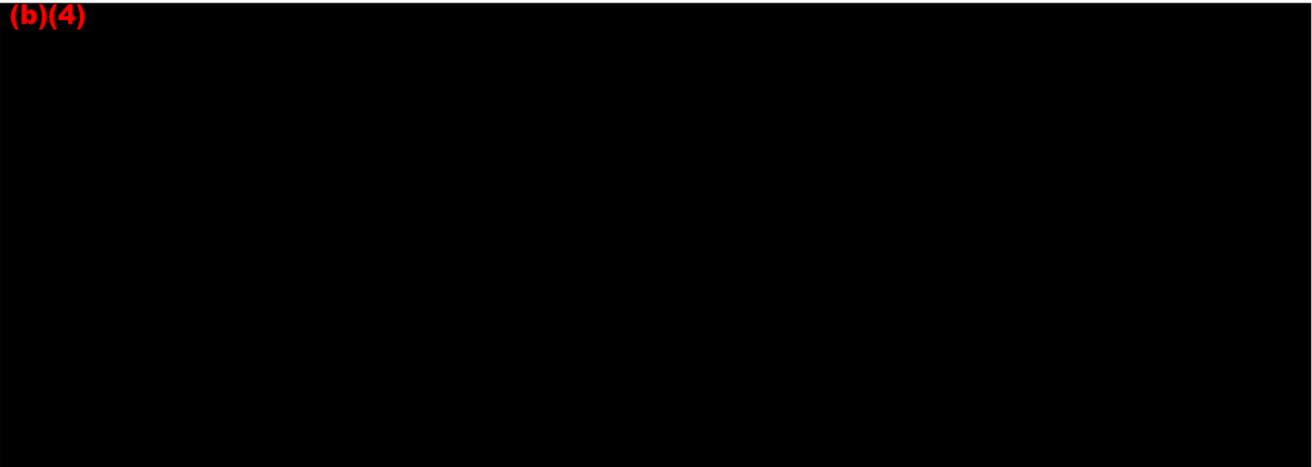
Cited predicate devices:

K073638 – Swift LT, ResMed Ltd.

K050359 – Ultra Mirage II Mask, ResMed Ltd.



(b)(4)



**Reviewer Comments:** *There are minimal differences between the cited predicate devices and the subject device. The flow, pressure, and dead space all are within the specifications of the predicate devices.*

**VI. Labeling**

The labeling for the Swift FX is provided in Section 13 of the submission. The labeling includes a User Manual and a Disinfection and Sterilization Guide. No advertising and/or promotional materials were included in the submission.

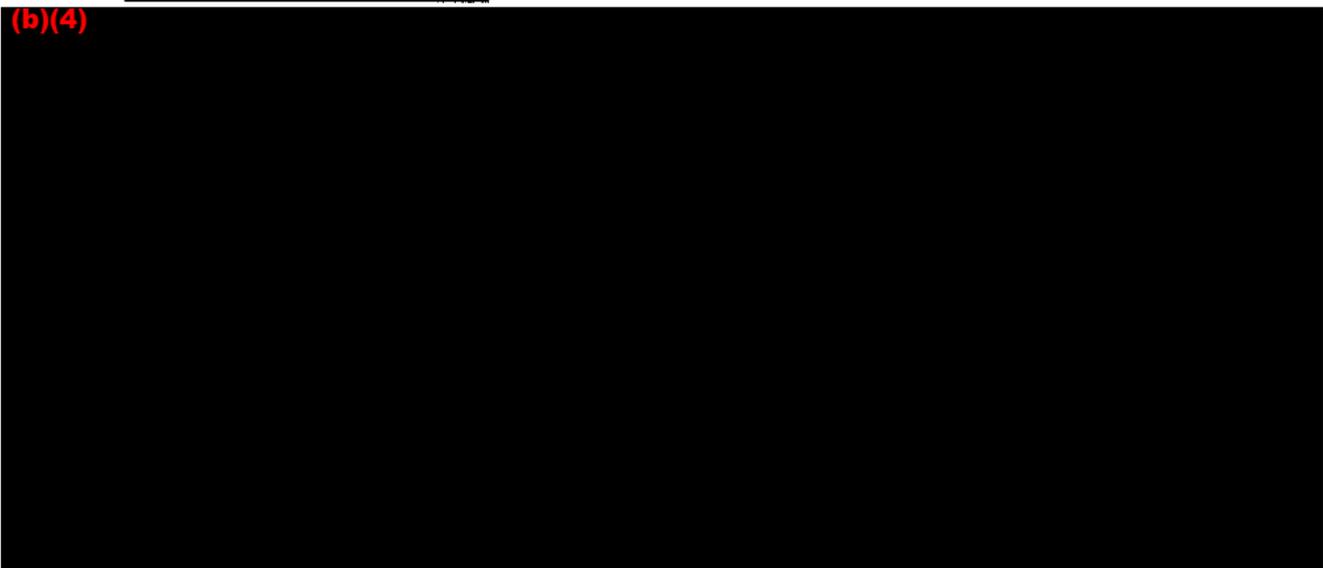
The User Manual is easily readable and provides the usual caution and warning statements for this classification of device.

The Disinfection and Sterilization Guide provides adequate instructions. The sponsor reports that this guide will be available to the hospitals/institutions via the manufacturer's website. The guide is reported as containing the same methods of reprocessing as the cleared predicate device by ResMed, the Swift LT (K073638).

**Reviewer Comments:** *The labeling provided is adequate, and the instructions for cleaning the mask are the same as with the previously cleared predicate device.*

**VII. Sterilization/Shelf Life/Reuse**

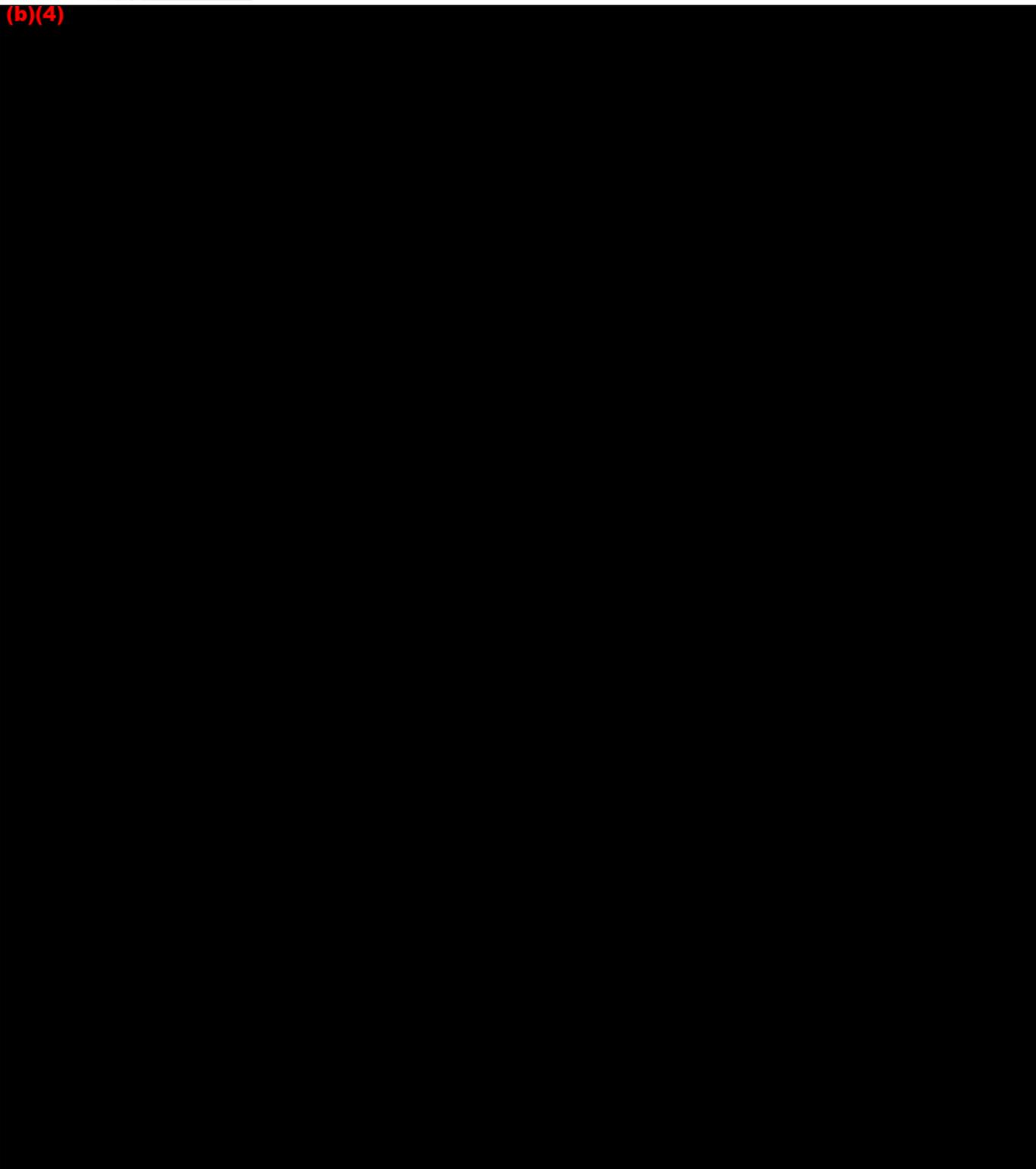
(b)(4)



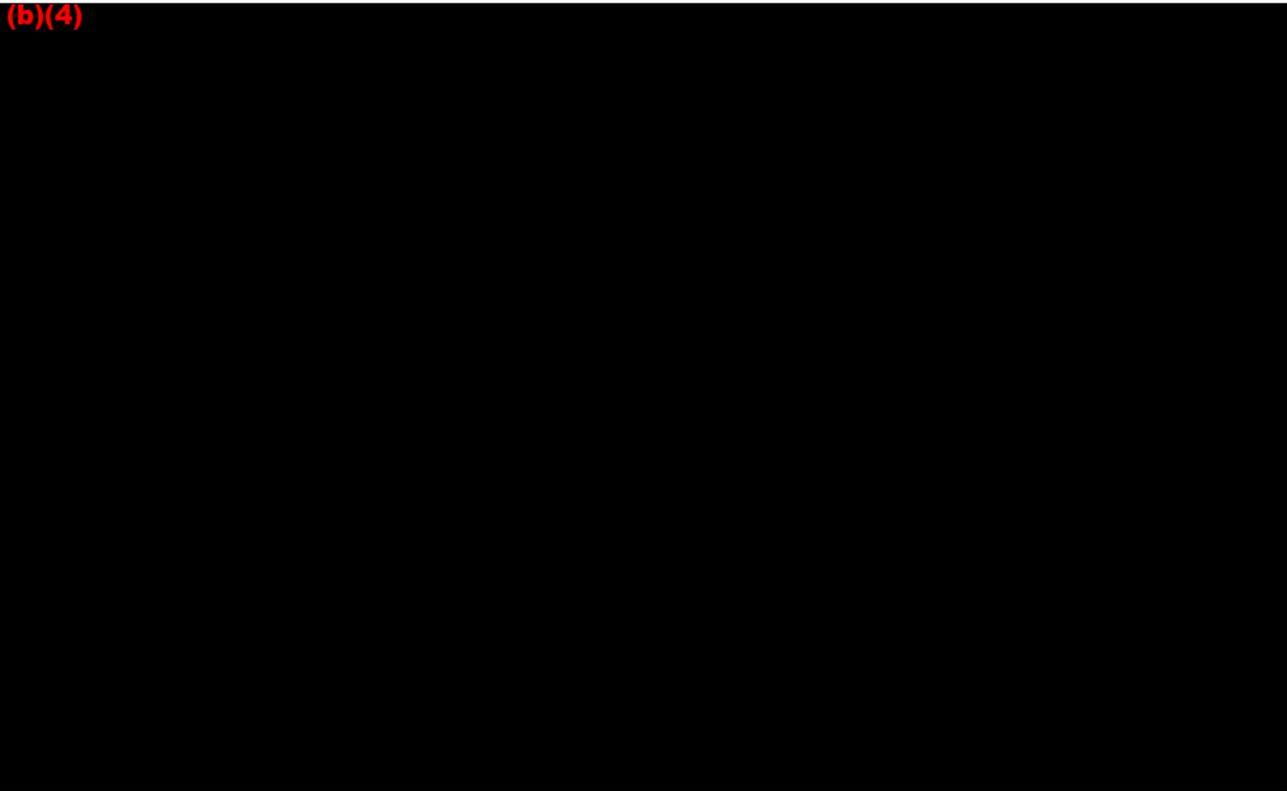
**Reviewer Comments:** *The labeling provided is adequate, and the instructions for cleaning the mask are the same as with the previously cleared predicate device. The sponsor's comparison to the predicate device as validation of the methods is reasonable.*

**VIII. Biocompatibility**

**(b)(4)**



(b)(4)



**Reviewer Comments:** *The sponsor has provided adequate rationale to support the lack of biocompatibility testing for the headgear back strap, and for the worst-case testing of the left and right head straps. The sponsor referenced a previous FDA determination for only providing cytotoxicity testing of the color change of the swivel ring. The previous file, K081321, had a biocompatibility consult from Ron Brown from OSEL. Because the biocompatibility expert had recommended only cytotoxicity testing be conducted in a similar color change scenario, the current testing is considered reasonable. No further biocompatibility issues remain.*

**IX. Software**

This device contains no software.

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

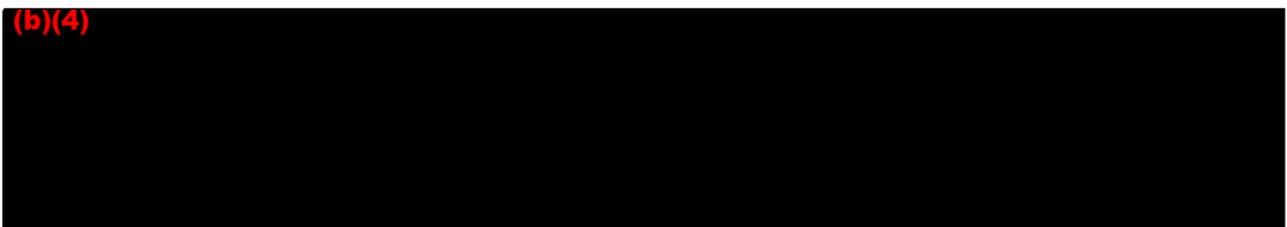
The device is not an electronic device.

**Mechanical:**

The sponsor provided information regarding the mechanical testing of the device in Section 18 of the submission. Further information regarding the mechanical testing of the mask can be found in the "Performance Testing – Bench" section of this memo.

**XI. Performance Testing – Bench**

(b)(4)



(b)(4)

*Reviewer Comments: The performance testing provided is adequate, and the sponsor has shown the device to be substantially equivalent to the cited predicate devices with respect to the usual performance parameters, including flow and dead space.*

**XII. Performance Testing – Animal**

No animal testing was conducted.

**XIII. Performance Testing – Clinical**

No clinical performance testing was conducted.

**XIV. Substantial Equivalence Discussion**

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

Note: See

[http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:

The performance of the new mask has to be shown through performance testing to evaluate the functions of the device.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

Bench testing of the mask are necessary for review to establish performance equal to the predicate devices.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The sponsor provided test data to show equivalence with the cited predicate devices for flow, resistance and dead space.

#### **XV. Deficiencies**

None noted.

#### **XVI. Contact History**

The above deficiencies were presented to the sponsor's representative via email on 8/15/07.

On 3/31/09, the sponsor's representative, David D'Cruz, was called to clarify a discrepancy in the file between the device components listed in the device description and those listed in the biocompatibility section of the submission. A swivel adapter is listed in the biocompatibility section with an accompanying biocompatibility certification statement, but this component is not listed in the device description. Also, the rationale behind the exceptions to the biocompatibility testing for the back strap (nylon/lycra mix) and the dyed swivel ring (grey) were discussed. Mr. D'Cruz stated he would discuss the file internally and address my inquiry via email.

On 4/1/09, Mr. D'Cruz emailed me to respond to my inquiry regarding the swivel adapter and the biocompatibility of the device. Mr. D'Cruz stated the swivel adapter is a component of the device and it was omitted from the description. Also, the biocompatibility of the back strap and the grey ring were explained. The email correspondence is attached to this memo.

#### **XVII. Recommendation**

I recommend this file be considered substantially equivalent to the cited predicate devices and be classified as:

Regulation Number: 21 CFR 868.5905  
Regulation Name: Accessory to Noncontinuous ventilator  
Regulatory Class: Class II  
Product Code: BZD

Charles M. Platts  
Reviewer

4/10/09  
Date

Susan Ruppel  
Branch Chief

4/13/09  
Date

**Kerns, Charles**

---

**From:** David D'Cruz [DavidD@ResMed.com]  
**Sent:** Wednesday, April 01, 2009 2:27 PM  
**To:** Kerns, Charles  
**Subject:** RE: K090244

Chuck,

Please find below our response to the questions we discussed yesterday.

Best regards,  
David.

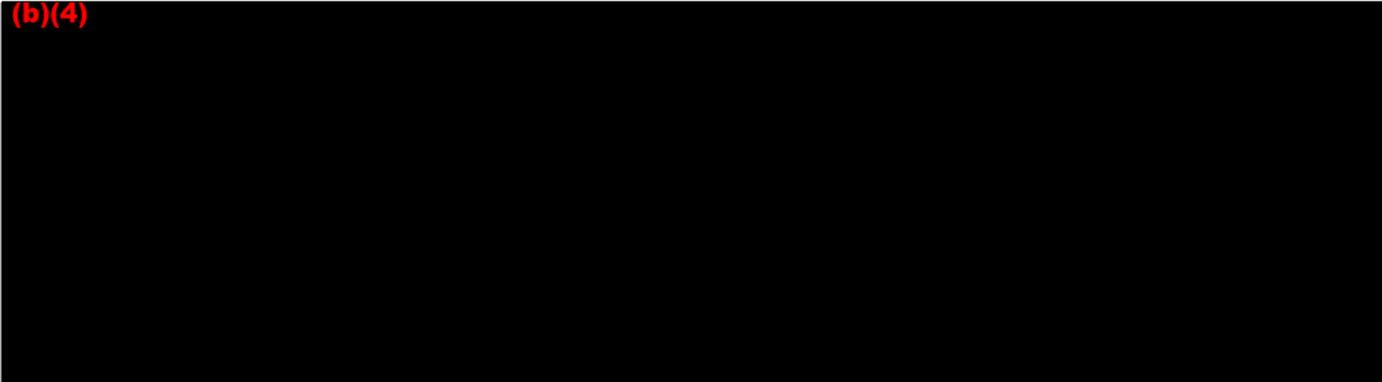
**1. Swivel adaptor**

Yes, omission of the swivel adaptor in the device description was an oversight. There is a very brief mention of the swivel adaptor at the very top of page 31. However, there was no detailed discussion in a separate paragraph. The design description of the swivel adaptor is now included below. ResMed apologize for this minor oversight.

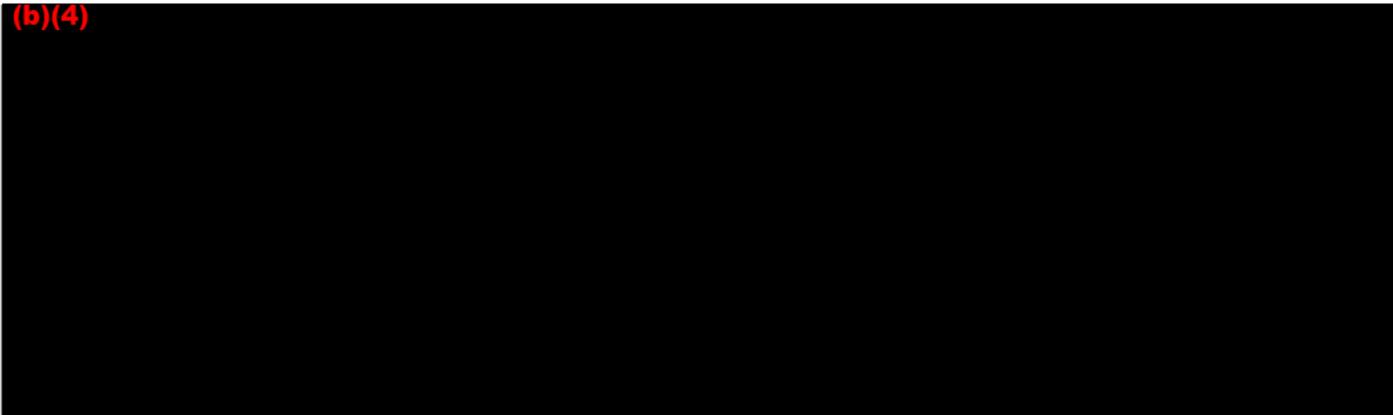
(b)(4)

**2. Page 65 - Navy Blue Headgear (back strap)**

(b)(4)

**3. Grey polycarbonate ring**

(b)(4)



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4/1/2009

14

**From:** Kerns, Charles [mailto:Charles.Kerns@fda.hhs.gov]  
**Sent:** Tuesday, March 31, 2009 6:03 AM  
**To:** David D'Cruz  
**Subject:** RE: K090244

Hello David,

Yes, I am reviewing the file, but am not finished yet. I have not seen any issues of concern yet.

I should complete the review in the next couple weeks.

Chuck

---

**From:** David D'Cruz [mailto:DavidD@ResMed.com]  
**Sent:** Monday, March 30, 2009 1:16 PM  
**To:** Kerns, Charles  
**Subject:** K090244

Dear Chuck,

I was wondering if you might be reviewing the above 510(k) which was received 2/2/09 as I'd like to get an update on its status please.

Thanks for your assistance.

Best regards,  
David.

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(b)(4)

4/1/2009