



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

April 16, 2014

TRUDELL MEDICAL INT'L
725 THIRD ST.
LONDON, ONTARIO
CANADA N5V 5G4
ATTN: DARRYL FISCHER

510k Number: K140919

Received: 4/15/14

Product: RESPICONNECT ADAPTER

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

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

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucml34034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

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

To learn more about the overall 510(k) Submission Process and types of interactions we will have with you during the review of your 510(k) submission, please refer to our website (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>).

If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

10903 New Hampshire Ave

Document Control Room WO66-G609

Silver Spring, MD 20993-0002



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BC: 20903105899 #2731-00709-18-42



CAIXMA



Trudell Medical International

725 Third Street, London, ON Canada N5V 5G4
 Telephone: +1-519-455-7060 • Fax: +1-519-455-6478

FAX COVER PAGE

To:	Document Control Center	From:	Darryl Fischer
Fax Number:	301 847 8133	Date:	Time:
Company:	FDA	If you have trouble reading this Fax, call: +1-519-455-7060	
Pages including header:	2 pages	Fax Number:	+1-519-455-6478

Confidentiality Note:

This message is intended for the use of the individual or entity to which it is addressed. This message may contain confidential, privileged or trade secret information that is exempt from disclosure under applicable law. If you are not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this message is strictly prohibited. If you have received this message in error, please notify us immediately for instructions on how and where to return this message. Thank you.

Re: **K140919**

Dear DCC Staff,

Please find attached a copy of the User Fee Cover Sheet as requested by your User Fee Hold Letter. The Payment Identification Number associated with the review of K140919 is (b)(4).

Our records indicate the payment has now been received by the FDA. If this is not the case for this review, please let me know as soon as possible.

Kind regards,

Darryl Fischer

Associate Director, Global Regulatory Affairs

A MEMBER OF THE TRUDELL MEDICAL GROUP
www.trudellmed.com

REGISTERED
 ISO 13485
 QUALITY SYSTEM

Records processed under FOIA Request # 2016-215; Released by CDRH on 03-15-2016

K 140919

Form Approved: OMB No. 0910-0311 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover-sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) TRUDELL MEDICAL INTERNATIONAL 725 Third Street London Ontario N5V 5G4 CA		2. CONTACT NAME Darryl Fischer 2.1 E-MAIL ADDRESS dfischer@trudellmed.com 2.2 TELEPHONE NUMBER (include Area code) 519-455-7060 2.3 FACSIMILE (FAX) NUMBER (include Area code) 519-455-6329	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm Select an application type:			
<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"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)			
<input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA		<input checked="" type="checkbox"/> 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? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm 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"/> The sole purpose of the application is to support conditions of use for a pediatric population	
<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 application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 (Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.)			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)			

27-Mar-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet



Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

K140919

21 March 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
APR 15 2014
Received

Re: **510(k) Notification**

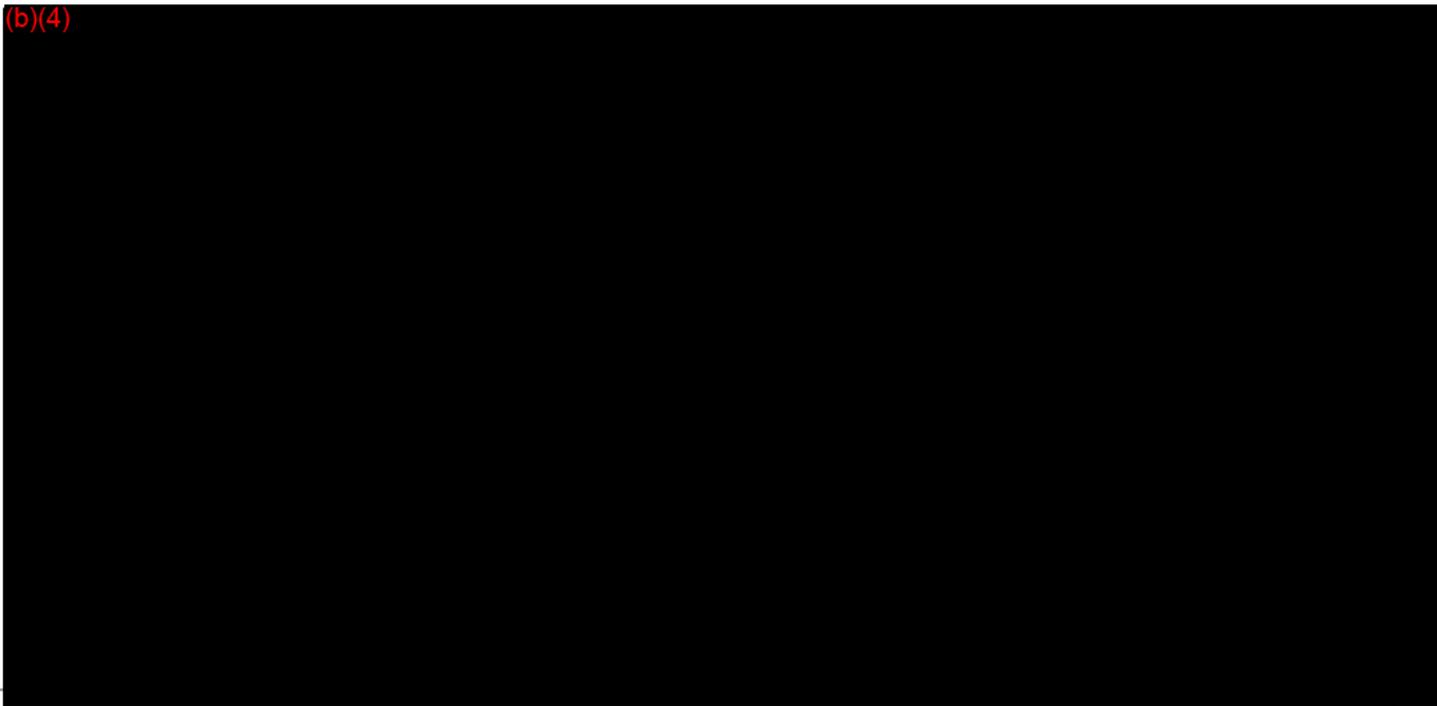
Dear Sir or Madam:

Herewith please find for your review a 510(k) Notification for the Adapter for *Respimat*™ Soft Mist Inhaler device. **The eCopy is an exact duplicate of the paper copy.**

Basis for Submission

This Premarket Notification for a **Class II** device has been prepared and submitted to demonstrate that the *RespiConnect*™ Adapter, an adapter not previously commercially distributed by our company in the United States, is at least as safe and effective as a legally marketed Class II device. The information has been assembled according to “**Format for Traditional and Abbreviated 510(k)s**”, issued August 12, 2005 (updated November 17, 2005), at the direction of FDA ODE Staff.

(b)(4)



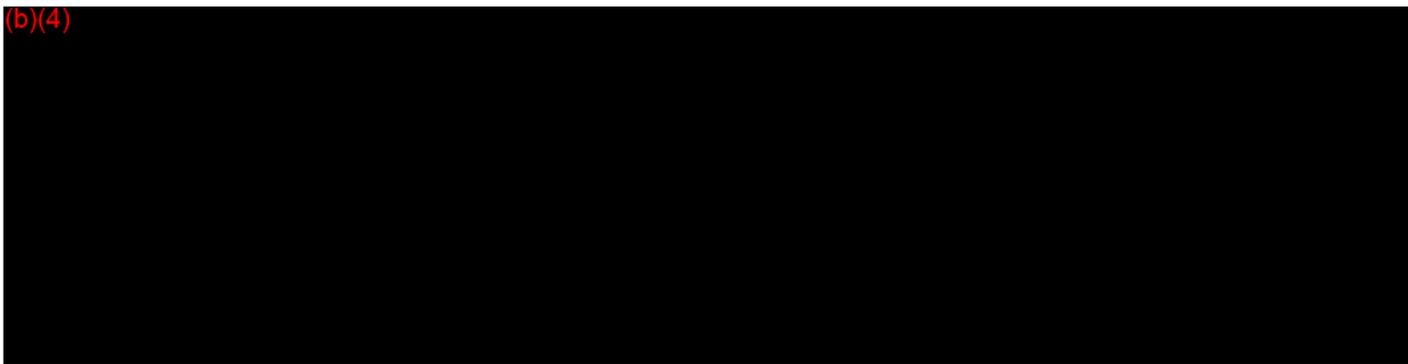
29



Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

(b)(4)



Accordingly, we have selected an appropriate predicate device and are submitting this new 510(k) application. Based upon the results contained within this submission, our device is substantially equivalent to the predicate device especially for the percentage (%) reduction of the Fine Particle Mass for albuterol and ipratropium bromide.

Type of 510(k) Submission	Traditional
Device Type	Accessory to a nebulizer
Product Code	CAF
510(k) Submitter	Trudell Medical International 725 Third Street London, Ontario N5V 5G4 CANADA
Contact Person	Darryl Fischer Associate Director, Global Regulatory Affairs Ph: 1-519-455-7060 ext 2140 Fax: 1-519-455-6329 e-mail: dfischer@trudellmed.com 868.5630
Recommended Classification Regulation	
Regulation Description	Nebulizer
Class	II
Panel	Anesthesiology



Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

Confidentiality Preference

In accordance with 21 CFR 807.95, I consider the intent to market this device confidential commercial information. Precautions have been taken to protect the confidentiality of the intent to market the device. I have not disclosed, nor to the best of my knowledge has anyone else disclosed the intent to market this device to any individual with the exception of employees of, or paid consultants to, this establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy. Should the intent be disclosed to individuals outside this exception, I will immediately notify the Food and Drug Administration. I understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Principal factors about design and use of the device

- Is the device intended for prescription use?
- Is the device intended for over-the-counter use?
- Does the device contain components derived from a tissue or other biologic source?
- Is the device provided sterile?
- Is the device intended for single use?
- Is the device a reprocessed single use device?
If yes, does this device type require reprocessed validation data?
- Are cleaning instructions included for the end user?
- Does the device contain a drug?
- Does the device contain a biologic?
- Does the device use software?
- Does the submission include clinical information?
- Is the device implanted?

YES	NO
X	
	X
	X
	X
	X
	X
	N/A
	X
	X
	X
	X
	X
	X

Should you have any questions or comments please feel free to contact me at your earliest convenience.

Kind regards,

Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International



Trudell Medical International

Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

K140919

21 March 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

APR 10 2014

Received

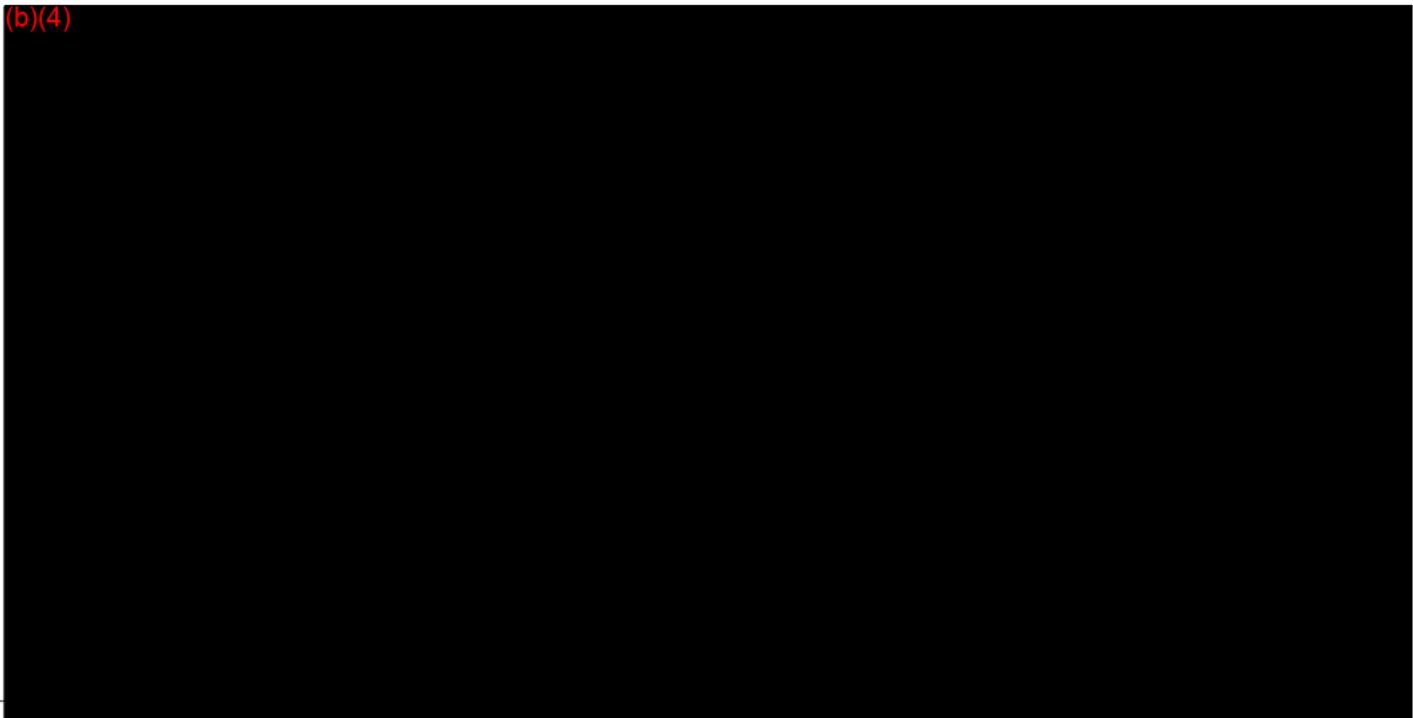
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(b)(4)

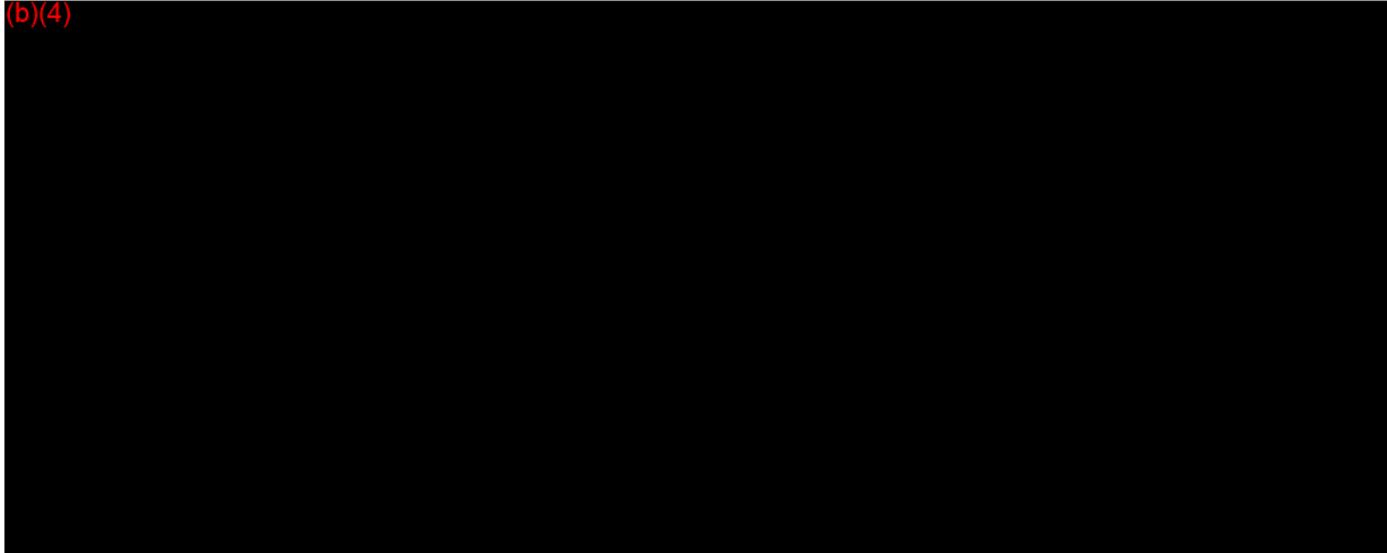


Trudell Medical International

Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

(b)(4)



Type of 510(k) Submission	Traditional
Device Type	Accessory to a nebulizer
Product Code	CAF
510(k) Submitter	Trudell Medical International 725 Third Street London, Ontario N5V 5G4 CANADA
Contact Person	Darryl Fischer Associate Director, Global Regulatory Affairs Ph: 1-519-455-7060 ext 2140 Fax: 1-519-455-6329 e-mail: dfischer@trudellmed.com
Recommended Classification Regulation	868.5630
Regulation Description	Nebulizer
Class	II
Panel	Anesthesiology



Trudell Medical International

Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

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If yes, does this device type require reprocessed validation data?
- Are cleaning instructions included for the end user?
- Does the device contain a drug?
- Does the device contain a biologic?
- Does the device use software?
- Does the submission include clinical information?
- Is the device implanted?

YES	NO
X	
	X
	X
	X
	X
	X
	N/A
	X
	X
	X
	X
	X
	X

Should you have any questions or comments please feel free to contact me at your earliest convenience.

Kind regards,

Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International

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CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 08 April 2014	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known) n/a
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SECTION A TYPE OF SUBMISSION

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Trudell Medical International	Establishment Registration Number (if known) 9612777		
Division Name (if applicable) n/a	Phone Number (including area code) +1 519 455 7060		
Street Address 725 Third Street	FAX Number (including area code) +1 519 455 6329		
City London	State / Province Ontario	ZIP/Postal Code N5V 5G4	Country Canada
Contact Name Darryl Fischer	Contact Title Associate Director, Global Regulatory Affairs	Contact E-mail Address dfischer@trudellmed.com	

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

Company / Institution Name	Division Name (if applicable)	Phone Number (including area code)	
Street Address	FAX Number (including area code)		
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION D1

REASON FOR APPLICATION - PMA, FDP, OR HDE

- New Device
- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
 - Software/Hardware
 - Color Additive
 - Material
 - Specifications
 - Other (*specify below*)

- Location change:
 - Manufacturer
 - Sterilizer
 - Packager

- Process change:
 - Manufacturing Packaging
 - Sterilization
 - Other (*specify below*)

- Labeling change:
 - Indications
 - Instructions
 - Performance Characteristics
 - Shelf Life
 - Trade Name
 - Other (*specify below*)

- Report Submission:
 - Annual or Periodic
 - Post-approval Study
 - Adverse Reaction
 - Device Defect
 - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (*specify*):

SECTION D2

REASON FOR APPLICATION - IDE

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
 - Correspondent/Applicant
 - Design / Device
 - Informed Consent
 - Manufacturer
 - Manufacturing Process
 - Protocol - Feasibility
 - Protocol - Other
 - Sponsor

- Response to FDA Letter Concerning:
 - Conditional Approval
 - Deemed Approved
 - Deficient Final Report
 - Deficient Progress Report
 - Deficient Investigator Report
 - Disapproval
 - Request Extension of Time to Respond to FDA
 - Request Meeting
 - Request Hearing

- Report submission:
 - Current Investigator
 - Annual Progress Report
 - Site Waiver Report
 - Final

- Other Reason (*specify*):

SECTION D3

REASON FOR SUBMISSION - 510(k)

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (*specify*):

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	CAF	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached
 510 (k) statement

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K926301	ACE Aerosol Cloud Enhancer	DHD Diemolding, Healthcare Division
2			
3			
4			
5			
6			

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Accessory to a nebulizer

Trade or Proprietary or Model Name for This Device

Model Number

1	RespiConnect Adapter	1	n/a
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	K131539	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

CAF

C.F.R. Section (if applicable)

868.5630

Device Class

- Class I Class II
 Class III Unclassified

Classification Panel

Anesthesiology

Indications (from labeling)

The RespiConnect* Adapter is designed to be used along with RESPIMAT* Soft Mist Inhalers to facilitate the delivery of aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

415 Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3001610754	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Trudell Medical International		Establishment Registration Number 9612777		
Division Name (if applicable) n/a		Phone Number (including area code) +1 519 455 7060		
Street Address 725 Third Street		FAX Number (including area code) +1 519 455 6329		
City London		State / Province Ontario	ZIP Code N5V 5G4	Country Canada
Contact Name Darryl Fischer		Contact Title Associate Director, Global Regulatory Affairs		Contact E-mail Address dfischer@trudellmed.com

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
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(b)(4)



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

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	ISO 10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Fourth Edition	10/15/2009
2	ISO 10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third Edition	06/01/2009
3	ISO 10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third Edition	08/01/2010
4	ISO 5356-1	ISO	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets	Third Edition	05/15/2004
5					
6					
7					

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

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

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

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

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 5356-1:2004, Anaesthetic and Respiratory Equipment - Part 1: Cones and Sockets

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #1-62

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 5356-1:2004, Anaesthetic and Respiratory Equipment - Part 1: Cones and Sockets

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 5	SECTION TITLE Conical connectors made of materials other than metal	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED *
n/a

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 6.3	SECTION TITLE 22mm Latching connectors	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED *
n/a

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-1:2009, Biological evaluation of medical devices-Part1:Evaluation &Testing Within a Risk Management Process

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-179

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-1:2009, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within a Risk Management Process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 6.2.2.2	SECTION TITLE Cytotoxicity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------------	-------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *
n/a

DESCRIPTION

JUSTIFICATION

This device is categorized as: Surface device, Contact: mucosal membrane (indirect contact - air path), Contact Duration: B - Prolonged Exposure (> 24h to 30 d)

SECTION NUMBER 6.2.2.3	SECTION TITLE Delayed-type Hypersensitivity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED *
n/a

DESCRIPTION

JUSTIFICATION

This device is categorized as: Surface device, Contact: mucosal membrane (indirect contact - air path), Contact Duration: B - Prolonged Exposure (> 24h to 30 d)

SECTION NUMBER 6.2.2.4	SECTION TITLE Irritation (including intracutaneous reactivity)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED *
n/a

DESCRIPTION

JUSTIFICATION

This device is categorized as: Surface device, Contact: mucosal membrane (indirect contact - air path), Contact Duration: B - Prolonged Exposure (> 24h to 30 d)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Rockville, MD 20850

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FOOD AND DRUG ADMINISTRATION

OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on page 5.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 24 May 2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known) n/a
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SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input 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	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Trudell Medical International	Establishment Registration Number (if known) 9612777		
Division Name (if applicable) n/a	Phone Number (including area code) +1 519 455 7060		
Street Address 725 Third Street	FAX Number (including area code) +1 519 455 6329		
City London	State / Province Ontario	ZIP/Postal Code N5V 5G4	Country Canada
Contact Name Darryl Fischer			
Contact Title Associate Director, Global Regulatory Affairs		Contact E-mail Address dfischer@trudellmed.com	

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

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1**REASON FOR APPLICATION - PMA, PDP, OR IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software/Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<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"/> Packaging <input type="checkbox"/> Sterilization <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 Characteristics <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"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Other Reason (<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 <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	BZA	2		3		4		
5		6		7		8		

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	n/a - Class I device	Neb Tee Adapter Model #1743	Teleflex Medical / Hudson RCI
2	n/a - Class I device	Valved Tee Adapter Model #2061	Airlife (Carefusion 303, Inc.)
3	n/a - Class I device	Valved "T" Adapter Model #313-2061	Pulmodyne
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
Connector, Airway (Extension)

	Trade or Proprietary or Model Name for This Device	Model Number
1	Adapter	1 n/a
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 BZA	C.F.R. Section (if applicable) 868.5810	Device Class <input checked="" type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Anesthesiology		

Indications (from labeling)
 The Adapter is designed to be used along with Respimat Soft Mist Inhalers to facilitate the delivery of aerosol medication to mechanically ventilated patients. The single-patient use adapter is intended to be left in the inspiratory limb of a 22mm ventilator circuit.

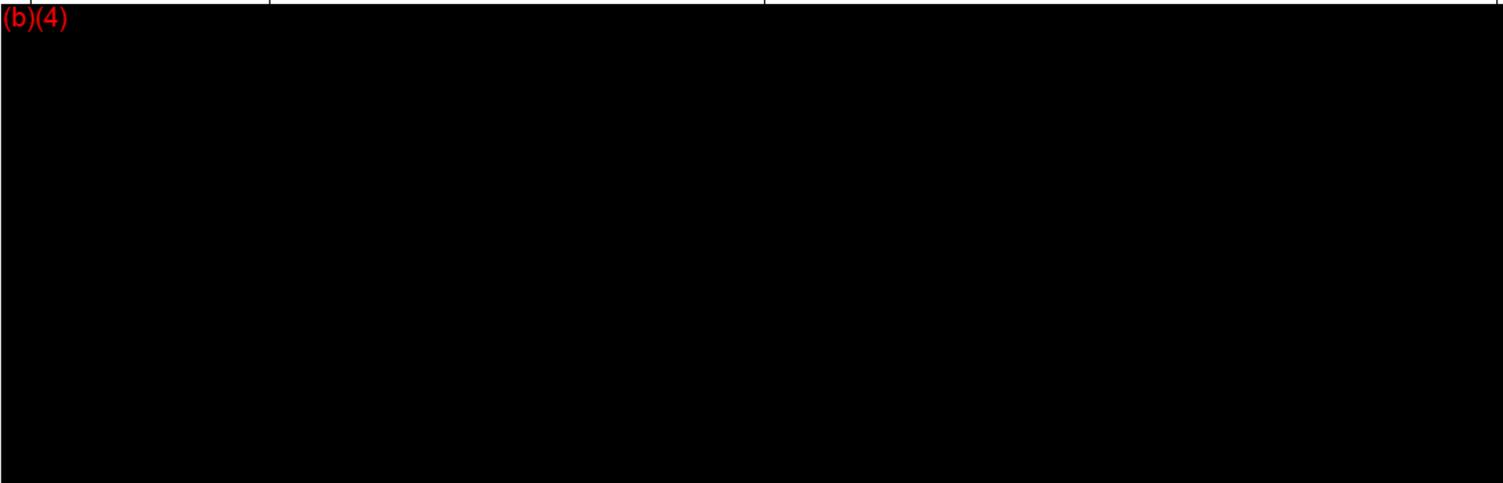
Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FD-3514 (1/13) (Instructions) (If known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3001610754	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
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Division Name (if applicable) n/a		Phone Number (including area code) +1 519 455 7060		
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Contact Name Darryl Fischer		Contact Title Associate Director, Global Regulatory Affairs		Contact E-mail Address dfischer@trudellmed.com

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(b)(4)

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

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Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-1:2009, Biological evaluation of medical devices-Part1:Evaluation &Testing Within a Risk Management Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#2-179	
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Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
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Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: _____		

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

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³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-1:2009, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within a Risk Management Process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2.2.2	Cytotoxicity	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦] n/a		
DESCRIPTION		
JUSTIFICATION This device is categorized as: Surface device, Contact: mucosal membrane (indirect contact - air path), Contact Duration: B - Prolonged Exposure (> 24h to 30 d)		
6.2.2.3	Delayed-type Hypersensitivity	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦] n/a		
DESCRIPTION		
JUSTIFICATION This device is categorized as: Surface device, Contact: mucosal membrane (indirect contact - air path), Contact Duration: B - Prolonged Exposure (> 24h to 30 d)		
6.2.2.4	Irritation (including intracutaneous reactivity)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦] n/a		
DESCRIPTION		
JUSTIFICATION This device is categorized as: Surface device, Contact: mucosal membrane (indirect contact - air path), Contact Duration: B - Prolonged Exposure (> 24h to 30 d)		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 5356-1:2004, Anaesthetic and Respiratory Equipment - Part 1: Cones and Sockets

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#1-62	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: _____		

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

² Authority [21 U S C 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 5356-1:2004, Anaesthetic and Respiratory Equipment - Part 1: Cones and Sockets

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 5	SECTION TITLE Conical connectors made of materials other than metal	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED ♦
n/a

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 6.3	SECTION TITLE 22mm Latching connectors	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED ♦
n/a

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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Rockville, MD 20850

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Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

21 March 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: **510(k) Notification**

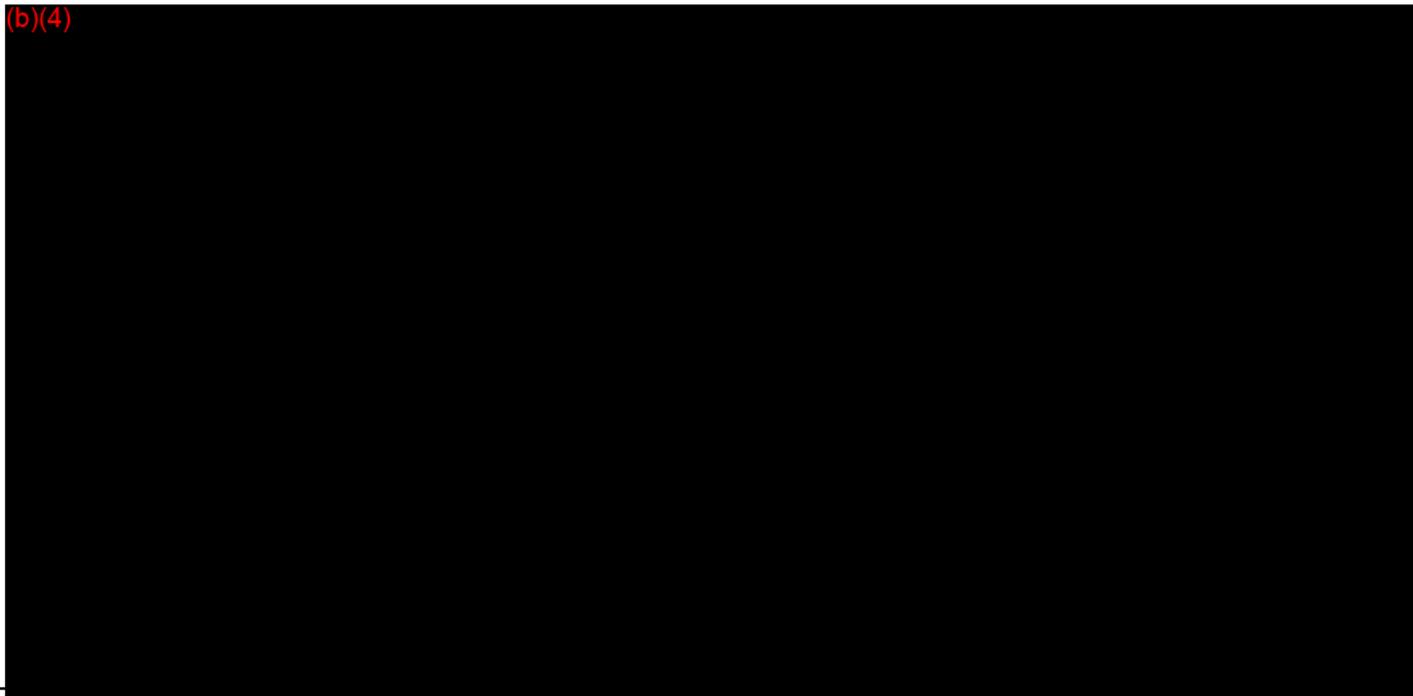
Dear Sir or Madam:

Herewith please find for your review a 510(k) Notification for the Adapter for *Respimat*™ Soft Mist Inhaler device. **The eCopy is an exact duplicate of the paper copy.**

Basis for Submission

This Premarket Notification for a **Class II** device has been prepared and submitted to demonstrate that the *RespiConnect*™ Adapter, an adapter not previously commercially distributed by our company in the United States, is at least as safe and effective as a legally marketed Class II device. The information has been assembled according to “**Format for Traditional and Abbreviated 510(k)s**”, issued August 12, 2005 (updated November 17, 2005), at the direction of FDA ODE Staff.

(b)(4)





Premarket Notification 510(k)
Adapter for Respimat™

Section 3 – Cover Letter

(b)(4)

Accordingly, we have selected an appropriate predicate device and are submitting this new 510(k) application. Based upon the results contained within this submission, our device is substantially equivalent to the predicate device especially for the percentage (%) reduction for the Fine Particle Mass for albuterol and ipratropium bromide.

Type of 510(k) Submission	Traditional
Device Type	Accessory to a nebulizer
Product Code	CAF
510(k) Submitter	Trudell Medical International 725 Third Street London, Ontario N5V 5G4 CANADA
Contact Person	Darryl Fischer Associate Director, Global Regulatory Affairs Ph: 1-519-455-7060 ext 2140 Fax: 1-519-455-6329 e-mail: dfischer@trudellmed.com
Recommended Classification Regulation	868.5630
Regulation Description	Nebulizer
Class	II
Panel	Anesthesiology



Premarket Notification 510(k)
 Adapter for Respimat™

Section 3 – Cover Letter

Confidentiality Preference

In accordance with 21 CFR 807.95, I consider the intent to market this device confidential commercial information. Precautions have been taken to protect the confidentiality of the intent to market the device. I have not disclosed, nor to the best of my knowledge has anyone else disclosed the intent to market this device to any individual with the exception of employees of, or paid consultants to, this establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy. Should the intent be disclosed to individuals outside this exception, I will immediately notify the Food and Drug Administration. I understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Principal factors about design and use of the device

	YES	NO
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Are cleaning instructions included for the end user?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Should you have any questions or comments please feel free to contact me at your earliest convenience.

Kind regards,

Darryl Fischer
 Associate Director, Global Regulatory Affairs
 Trudell Medical International

Indications for Use

510(k) Number: _____

Device Name:

Indications for Use:

The RespiConnect Adapter is designed to be used along with **RESPIMAT™** SOFT MIST INHALERS to facilitate the delivery of aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Page 1 of 1

* Trade marks and registered trademarks of Trudell Medical International

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

Section 5 – 510(k) Summary

Prepared: 21 March 2014

510(k) Owner Trudell Medical International
 725 Third Street
 London, Ontario N5V 5G4
 CANADA

Contact Person Darryl Fischer
 Associate Director, Global Regulatory Affairs

Phone 1-519-455-7060 ext 2140
Fax 1-519-455-6329
e-mail dfischer@trudellmed.com

Device Name

Proprietary RespiConnect Adapter
 Common/Classification Accessory to a nebulizer

Product Code CAF

Classification Regulation 868.5630

Predicate Device(s) 510(k) Number	Trade/Model Name	Manufacturer
K926301	Ace Cloud Enhancer	DHD Diemolding, Healthcare Division

Device Description

The RespiConnect Adapter is a single-patient use device intended to provide a self-sealing access port in a ventilator circuit to facilitate the administration of **Respimat™** Soft Mist inhaler medication to mechanically ventilated patients.

Intended Use

The RespiConnect Adapter is designed to be used to facilitate the delivery of aerosol medication from a **Respimat™** Soft Mist Inhaler to mechanically ventilated patients. The single-patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit once installed

* Trademarks and registered trademarks of Trudell Medical International

Section 5 – 510(k) Summary

The intended use does not differ significantly from that of the predicate device detailed below. The predicate device below is designed to assist with the delivery of aerosolized medications from metered dose inhaler canisters to a mechanically ventilated patient.

Ace Aerosol Cloud Enhancer, K926301	
<ul style="list-style-type: none">• Manufactured from plastic• 22mm OD and ID fittings to accommodate 22 mm breathing circuit connections• Used to administer aerosolized medication to a mechanically ventilated patient	



Section 5 – 510(k) Summary

Technological Characteristic Comparison to Predicate Device

The table below presents some of the common device characteristics exhibited by the Class II device and the predicate device.

Common Device Characteristics		
Characteristic	 RespiConnect Adapter for Respimat™	 ACE Aerosol Cloud Enhancer K926301
Single Patient Use	Yes	Yes
For use in a ventilator circuit	Yes	Yes
Delivery of aerosol medication	Yes	Yes
Built in actuator	No	Yes
Sold non-sterile	Yes	Yes
22mm ISO fittings	Yes	Yes
Device Classification:	Class II – Accessory to a nebulizer	Class II – Accessory to a nebulizer

Relevant differences in the operating principles of the Adapter for Respimat™ and the predicate device;

- RespiConnect Adapter is used only with the Respimat™ Soft Mist Inhaler (SMI) device.
- RespiConnect Adapter has a self-sealing port to maintain circuit integrity once the Respimat™ device is removed. The ACE device must be capped to prevent circuit leakage if it remains in the circuit after use.
- RespiConnect Adapter remains in the circuit once installed, and is discarded with the circuit upon circuit change. The ACE device is not recommended to remain in the circuit once in place, and may be removed after each use.
- RespiConnect Adapter has a molded arrow to indicate direction of air flow. The ACE device is not labeled with the direction of air flow.

Section 5 – 510(k) Summary

- RespiConnect Adapter is not patient-orientation sensitive while medication is being delivered. The ACE device and pMDI is patient-orientation sensitive during aerosol delivery, as the pMDI must be oriented in the upright position during firing to ensure the labeled dosage of drug is properly delivered.

Non-Clinical Test Summary

Mechanical testing was conducted to characterize the operating parameters (leakage) of the RespiConnect Adapter device. The results (in Section 11, Attachment 4) demonstrate that the RespiConnect Adapter device performs satisfactorily, and does not raise any new safety or efficacy related issues.

There are no direct patient contacting components of the RespiConnect Adapter device. However, the materials of construction were tested for biocompatibility and do meet the requirements of ISO 10993-1:2009, Biological evaluation of medical devices.

Biological evaluation of the RespiConnect Adapter device was classified according to the requirements within ISO 10993-1 as follows;

- Category: Surface device
- Contact: Mucosal membranes
- Contact Duration: B – Prolonged Exposure (24hrs to 30 days)
- Evaluation Testing for Biological Effect
 - Cytotoxicity – according to ISO 10993-5
 - Sensitization – according to ISO 10993-10
 - Irritation or Intracutaneous Reactivity - according to ISO 10993-10

Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance Data.

Conclusions from Testing

The RespiConnect Adapter device has been compared against a currently marketed (predicate) device for the determination of substantial equivalency. The RespiConnect Adapter device and the predicate device share:

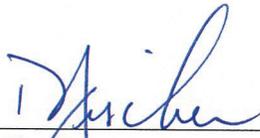
- common indications for use for mechanically ventilated patients
- usage environments
- both devices are single patient use
- both devices are sold non-sterile

Section 5 - 510(k) Summary

The RespiConnect Adapter device raises no new issues regarding safety or efficacy.

Section 6 – Truthful and Accurate Statement

I certify that, in my capacity as Associate Director, Global Regulatory Affairs, of Trudell Medical International, 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.



Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International



Date

Section 7 – Class III Summary and Certification

This Premarket Notification 510(k) is for a Class II device, therefore, a Class III Summary and Certification is not required.

Section 8 – Financial Certification or Disclosure Statement

This Premarket Notification 510(k) does not contain information from clinical studies. The determination of substantial equivalence is not based on an assessment of Clinical Performance Data. Therefore, neither a Financial Certification nor a Clinical Investigator Disclosure Statement is required.

Premarket Notification 510(k)
RespiConnect Adapter

Trudell Medical International

Section 9 – Declarations of Conformity and Summary Reports

Verification Activities

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

(b) (6)
[Redacted Signature]

Director, New Product Development
Trudell Medical International

Date 8 Apr 2014

Manufacturing Facility

The manufacturing facilities are in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Darryl Fischer
Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International

Date 08 Apr 2014

Premarket Notification 510(k)
RespiConnect Adapter

Trudell Medical International

Section 9 – Declarations of Conformity and Summary Reports

Environmental Conditions

The RespiConnect Adapter conforms to the following mechanical testing recommendations, described in the “Reviewer’s Guidance for Premarket Notification” (November 1993). The device has demonstrated to operate within its specifications during and after operating in the environmental range of 15° C. to 40° C. and in the environmental humidity range of 15% to 95% (non-condensing). Reference DCRND/ARDB Reviewers Guidance Appendix A(i)(6)(i)

(b)(6)

Director, New Product Development
Trudell Medical International

Date 8 Apr 2014

Section 10 – Executive Summary

Device Description

The RespiConnect Adapter device is a single-patient use connector intended to provide a self-sealing access port in the inspiratory limb of a ventilator circuit to facilitate the administration of **Respimat™** Soft Mist inhaler medications to mechanically ventilated patients.

Intended Use

The RespiConnect Adapter device is designed to be used to along with Respimat™ Soft Mist Inhalers to facilitate the delivery of aerosol medication to mechanically ventilated patients. The single-patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

The above intended use does not differ significantly from that of the predicate devices detailed below. The predicate device is intended to be used in inspiratory limb of a ventilator circuit, for the purpose of administering aerosolized medication to a mechanically ventilated patient.

- ACE Aerosol Cloud Enhancer – K926301
- Manufactured from plastic
- 22mm OD and ID fittings to accommodate 22 mm breathing circuit connections



Section 10 – Executive Summary

Substantial Equivalence Comparison Table

The table below presents some of the common device characteristics exhibited by the Class II device and the predicate device.

Common Device Characteristics		
Characteristic	 RespiConnect Adapter	 ACE Aerosol Cloud Enhancer K926301
Single Patient Use	Yes	Yes
For use in a ventilator circuit	Yes	Yes
Delivery of aerosol medication	Yes	Yes
Built in actuator	No	Yes
22mm ISO Fittings	Yes	Yes
Device Classification	Class II – Accessory to a nebulizer	Class II – Accessory to a nebulizer

Relevant differences in the operating principles of the RespiConnect Adapter device and the predicate device(s);

- RespiConnect Adapter is used only with the Respimat™ Soft Mist Inhaler (SMI) device.
- RespiConnect Adapter has a self-sealing port to maintain circuit integrity once the Respimat™ device is removed. The ACE device must be capped to prevent circuit leakage if it remains in the circuit after use.
- RespiConnect Adapter remains in the circuit once installed, and is discarded with the circuit upon circuit change. The ACE device is not recommended to remain in the circuit once in place, and may be removed after each use.
- RespiConnect Adapter has a molded arrow to indicate direction of air flow. The ACE device is not labeled with the direction of air flow.

Section 10 – Executive Summary

RespiConnect Adapter is not patient-orientation sensitive while medication is being delivered. The ACE device and pMDI is patient-orientation sensitive during aerosol delivery, as the pMDI must be oriented in the upright position during firing to ensure the labeled dosage of drug is properly delivered.

Non-Clinical Test Summary

Mechanical testing was conducted to characterize the operating parameters (installation, leakage, etc.) of the RespiConnect Adapter device.

Mechanical testing consisted of the following;

- Simulated use
- Environmental limit testing (operating limits and environmental storage and transportation testing)
- Drop testing
- Connection leakage
- Fatigue and torsional testing
- Circuit resistance testing

The results (b)(4) demonstrate that the RespiConnect Adapter performs in the same fashion to the predicate device, and does not raise any new safety or efficacy related issues.

There are no direct patient contacting components of the RespiConnect Adapter. However, the materials of construction do meet the requirements of ISO 10993-1:2009, Biological evaluation of medical devices.

Biological evaluation of RespiConnect Adapter device was classified according to the requirements within ISO 10993-1 as follows;

- Category: Surface device
- Contact: Mucosal membranes
- Contact Duration: B – Prolonged Exposure (24hrs to 30 days)
- Evaluation Testing for Biological Effect
 - Cytotoxicity – according to ISO 10993-5
 - Sensitization – according to ISO 10993-10
 - Irritation or Intracutaneous Reactivity - according to ISO 10993-10

Clinical Performance Summary

Section 10 – Executive Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance Data.

Conclusions from Testing

The RespiConnect Adapter device has been evaluated against a currently marketed (predicate) device for the determination of substantial equivalency. The RespiConnect Adapter device and the predicate devices share:

- common indications for use
- usage environments
- both devices are single patient use
- non-sterile

The RespiConnect Adapter device raises no new issues regarding safety or efficacy.

Section 11 – Device Description

Principal Factors of Design and Use

	YES	NO
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Are cleaning instructions included for the end user?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Performance Specifications

Functional requirements for the RespiConnect Adapter are specified in the Product Design Specification (b)(4)

Device Design Requirements

Risk Analysis in accordance with ISO 14971:2007 was performed on the RespiConnect Adapter and its subcomponents using Design Failure Mode and Effects Analysis (DFMEA) methodology.

The design characteristics of the RespiConnect Adapter were evaluated against verification test protocols which are described in (b)(4)

Design verification test results are reported in (b)(4)

A Declaration of Conformity with Design Controls has been prepared and is included in Section 9 of this submission.

Section 11 – Device Description

Identification of Models

The RespiConnect Adapter is offered as a single product configuration as described within this submission.

Identification of Accessories

No accessories are currently recommended for use with the RespiConnect Adapter

Identification of Components

Five (5) components comprise the RespiConnect Adapter. The configuration is depicted in Assembly Drawing (b)(4) 

Patient-Contacting Components and their Respective Materials

There are no patient contacting components of this device. Identification of device components and their respective materials can be found in section 15 of this submission.

Premarket Notification 510(k)
Adapter for Respimat™

Trudell Medical International

Section 11 - Device Description

Attachment 1 - Performance Specifications

Document Title: Product Design Specification

Document Number: (b)(4)

Section 11
Attachment 1

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Section 11 - Attachment 1 - Page 1 of 4
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

Premarket Notification 510(k)
Adapter for Respimat™

Trudell Medical International

Section 11 - Device Description

Attachment 2 - Device Test Plan

Document Title: Test Plan

Document Number: (b)(4)

Section 11
Attachment 2

Premarket Notification 510(k)
Adapter for Respimat™

Trudell Medical International

Section 11 - Device Description

Attachment 3 - Device Test Report

Document Title: Test Report

Document Number: (b)(4)

Section 11
Attachment 3

Premarket Notification 510(k)
Adapter for Respimat™

Trudell Medical International

Section 11 - Device Description

Attachment 4 - Device Test Report

Document Title: Test Report

Document Number: (b)(4) Test Report

Section 11
Attachment 4

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Section 11 - Attachment 4 - Page 1 of 6
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

Premarket Notification 510(k)
Adapter for Respimat™

Trudell Medical International

Section 11 - Device Description

Attachment 5 - Identification of Components

Document Title: Assembly Drawing

Document Number: (b)(4)

Section 11
Attachment 5

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

Section 11 - Device Description

Attachment 6 - Identification of Components

Document Title:

(b)(4) Testing

Document Number:

Section 12 – Substantial Equivalence Discussion

Predicate Info (where available)

Predicate Device 510(k) Number	Trade Name	510(k) Holder
K926301	ACE Aerosol Cloud Enhancer	DHD Diemolding, Healthcare Division

Indications for use

The RespiConnect Adapter is designed to be used along with RESPIMAT™ SOFT MIST INHALER formulations to facilitate the delivery of aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

Technology

The RespiConnect Adapter device is intended to be used by patients who are under the care or treatment of a health care provider or physician. The device is intended to be used to administer aerosolized medication from the RespiMat™ Soft Mist Inhaler, prescribed by a physician or health care professional. The intended environments for use include hospitals and clinics.

The Intended Use and Indications of the RespiConnect Adapter device, as described in the its labeling included in this submission in Section 4, are comparable to the predicate Class II device currently available on the market.

The RespiConnect Adapter device has been evaluated against the currently marketed (predicate) device for the determination of substantial equivalency. As outlined in the Substantial Equivalence Comparison Table found on page 3 of Section 10, the RespiConnect Adapter device and the predicate device share common indications for use, and usage environments. The devices are single patient use, non-sterile devices available by prescription.

Section 12 – Substantial Equivalence Discussion

The device characteristics of the RespiConnect Adapter have been evaluated against the predicate device cleared as a Class II device. The Substantial Equivalence Comparison Table found in Section 10, page 3, highlights the common device characteristics of the devices. As highlighted in the design control summary and supported by the risk analysis and verification testing referenced in Section 11, the characteristics of the RespiConnect Adapter have been evaluated to ensure no new safety or effectiveness questions have been raised.

Summary

The information provided in this section demonstrates that the differences between the RespiConnect Adapter device and the predicate device raise no new issues of safety and effectiveness.

Section 13 – Proposed Labeling

The proposed labeling for the Adapter for Respimat™ is attached.

RespiConnect*

Adapter for RespiMat® Soft Mist® Inhaler



Trudell Medical International*

725 Third Street, London, Ontario, Canada N5V 5G4
 + 519-455-7060
 customerservice@trudellmed.com
 www.trudellmed.com



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US Hospital Distribution
 Monaghan Medical Corporation
 5 Latour Avenue, Suite #1600, Plattsburgh, NY, USA 12901

REF 112501



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The **RespiConnect*** adapter is designed to be used along with RESPIMAT® SOFT MIST INHALER formulations to facilitate the delivery of aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

The device is not intended to be cleaned between uses.

CAUTION: The **RespiConnect*** adapter is designed for use only in the inspiratory limb of a ventilator circuit. Use in any other part of the ventilator circuit is not recommended.

WARNING:

- SINGLE PATIENT USE
- CHANGE WITH CIRCUIT
- DO NOT STERILIZE
- DO NOT REUSE
- DO NOT USE NEAR STRONG MAGNETIC FIELD

DIMENSIONS

Overall Length	3.75 inches
Overall Height	2.25 inches
O.D. / I.D.	22 mm

Cascade Impactor Data for RESPIMAT® Soft Mist® Inhaler with RespiConnect* Adapter

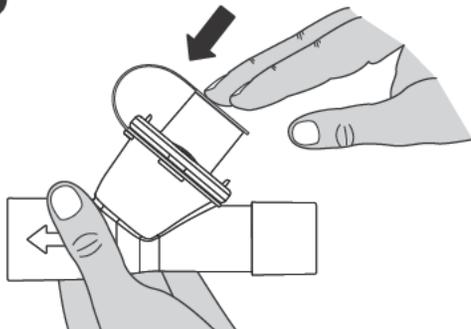
	Albuterol	Ipratropium Bromide
Total Delivered Dose (µg)	42.3	8.2
Respirable Fraction (0.4 – 4.7µm aerodynamic diameter) (%)	60.3	63.5
Respirable Particle Mass (µg)	25.5	5.2

For reference only. N=5 devices. Cascade Impactor testing conducted at 28.3 lpm.



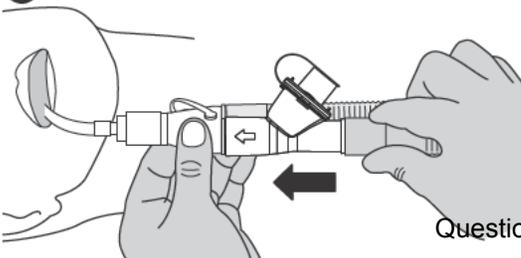
INSTALLATION INSTRUCTIONS

1



Remove the **RespiConnect*** adapter from its packaging and inspect for damage or missing components.
 Place cap on adapter ensuring it is firmly closed.
 The adapter can be used right out of package. Before use, ensure these instructions and the instructions supplied with the RESPIMAT® SOFT MIST® INHALER have been read and are kept available at all times.

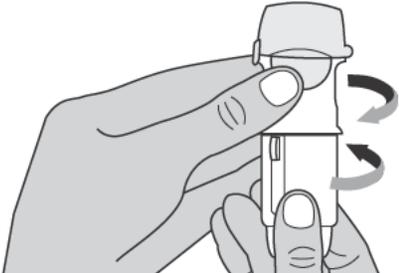
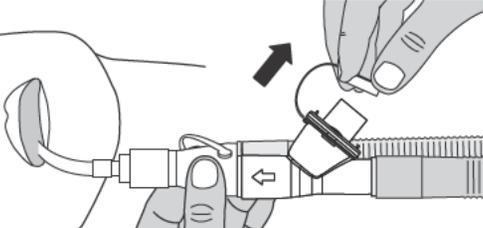
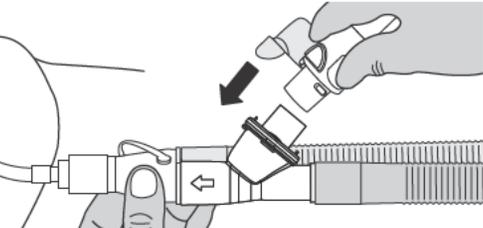
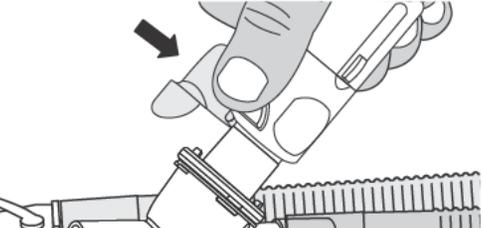
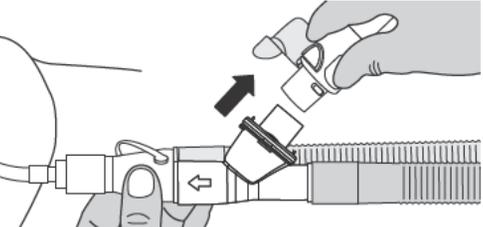
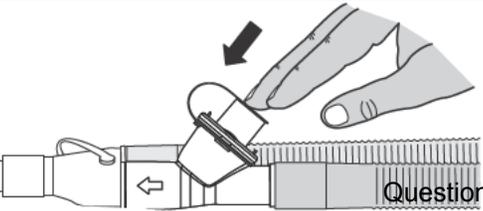
2



Insert the **RespiConnect*** adapter into the inspiratory limb of the circuit as shown. Ensure the Wye Connector end is attached to the wye and that the arrow on the adapter is pointing towards the patient.
CAUTION: To avoid circuit disconnects, ensure connections are properly secured as intended.

INSTRUCTIONS FOR USE

LOREM IPSUM LOREM IPSUM
LOREM

	<p>Follow priming instructions for the RESPIMAT[®] SOFT MIST[®] INHALER as outlined in the instructions for use.</p> <div style="border: 1px solid red; padding: 5px; color: red;"> <p>The RESPIMAT[®] SOFT MIST[®] INHALER must be primed in an upright position (per the instructions supplied with the inhaler) before being inserted into the adapter.</p> </div>	
	<p>Remove the cap from the adapter as shown.</p>	
	<p>Flip the cap on the RESPIMAT[®] SOFT MIST[®] INHALER until it snaps fully open. Fully insert the RESPIMAT[®] SOFT MIST[®] INHALER into the <i>RespiConnect</i>[®] adapter as shown.</p>	
	<p>At the onset of inspiration, press the dose release button on the RESPIMAT[®] SOFT MIST[®] INHALER.</p>	
	<p>After medication administration, remove the RESPIMAT[®] SOFT MIST[®] INHALER from the adapter.</p>	
	<p>Place cap on adapter ensuring it is firmly closed. The adapter is designed to be left in the ventilator circuit. If additional dose is required, repeat steps 1–6.</p>	

Section 14 – Sterilization and Shelf Life

The RespiConnect Adapter device is not sold as sterile, nor does the submission identify a shelf life. The requirements of Section 14 – Sterilization and Shelf Life do not apply.

Normal storage and transportation conditions (humidity and temperature extremes) have been evaluated as part of the verification testing in (b)(4) and the results demonstrate these conditions will not affect the safety of effectiveness of the device.

Section 15 – Biocompatibility

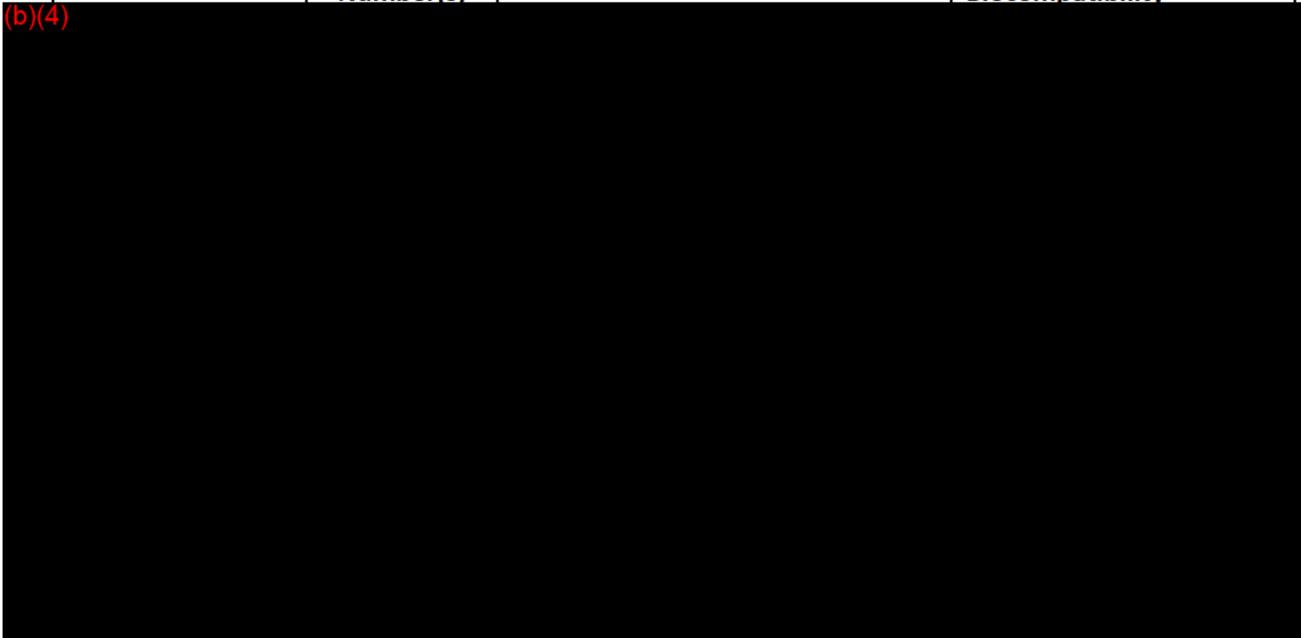
The plastic components of the Adapter for Respimat™ have been evaluated in accordance with Blue Book Memo G95-1 “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” (May 1995). No components of the Adapter for Respimat™ have direct patient contact.

A description of each component that has indirect (air-path) patient contact along with evidence of biocompatibility is provided in Table 1 of this section.

TABLE 1: In-direct Patient Contacting Components

Nature of Body Contact: (in accordance with section 5.2 of ISO 10993-1 Fourth edition 2009-10-15) Category: Surface device Contact: Mucosal membrane (indirect - air path)			
Contact Duration: (in accordance with section 5.3 of ISO 10993-1 Fourth edition 2009-10-15) Prolonged exposure (B) – cumulative single, multiple or repeated long-term use or contact is likely to exceed 24 h but not 30 d.			
Description	Part Number(s)	Material Identification	Evidence of Biocompatibility

(b)(4)



Section 15 – Biocompatibility Information

Attachment 1 – Biocompatibility Data

Document Type: Biocompatibility Report

Material: (b)(4)

Section 15 – Biocompatibility Information

Attachment 2 – Biocompatibility Data

Document Type: Biocompatibility Report

Material: (b)(4)

(b)(4) is the identical resin used in a previously cleared device (b)(4) as a component of assembly (b)(4) (attached).

Section 16 – Software

The RespiConnect Adapter device does not contain software. The requirements of Section 16 do not apply.

Section 17 – Electromagnetic Compatibility & Electrical Safety

The RespiConnect Adapter device does not include an electronic component, nor does the design result in patient contact with any electrically powered component. The requirements of Section 17 do not apply.

Section 18 – Performance Testing - Bench

Evaluation of the Adapter for Respimat* device and the predicate device was performed to characterize the device's operating performance. In accordance with the intended use, each device operates in-line with ventilator circuits attached to mechanical ventilators. The adapter provides an access port to the breathing circuit to facilitate physician-prescribed aerosolized medication to be administered to the patient as prescribed.

Mechanical safety testing consisted of the following;

- Simulated use
- Leakage testing
- Environmental limit testing (operating limits and environmental storage and transportation testing)
- Drop testing
- Connection leakage
- Fatigue and torsional testing
- Circuit resistance testing

The results of this testing is documented in (b)(4) Third Party Testing, Attachments (b) (4) respectively.

There are no direct patient contacting components of the Adapter for Respimat™ device. However, the materials of construction were tested for biocompatibility and do meet the requirements of ISO 10993-1:2009, Biological evaluation of medical devices.

Biological evaluation of Adapter for Respimat™ device was classified according to the requirements within ISO 10993-1 as follows;

- Category: Surface device
- Contact: Mucosal membranes (indirect patient contact)
- Contact Duration: B – Prolonged Exposure (24hrs to 30 days)
- Evaluation Testing for Biological Effect
 - Cytotoxicity – according to ISO 10993-5
 - Sensitization – according to ISO 10993-10
 - Irritation or Intracutaneous Reactivity - according to ISO 10993-10

The evaluation of these results present no new issues related to safety or efficacy of the Adapter for Respimat™ device.

Section 19 – Performance Testing - Animal

The determination of substantial equivalence is not based animal test results. Therefore, the requirements of Section 19 do not apply.

Section 20 – Performance Testing - Clinical

This Premarket Notification 510(k) does not contain information from clinical studies. The determination of substantial equivalence is not based on an assessment of Clinical Performance Data. Therefore, the requirements of Section 20 do not apply.

K140919/S00/

FDA CDRH DMC

MAY 05 2014

Received



Trudell Medical International

01 May 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Re: Refuse to Accept (RTA) issued for 510(k) K140919

Attention: Deepika Lakhani

Dear Deepika,

Please find attached TMI's response to your RTA Hold letter issued for 510(k) K140919. To facilitate your review, I have summarized our response in the same order in which they were identified on the RTA summary documentation.

Two copies of our response (1 eCopy and 1 paper copy), referencing the 510(k) number K140919, addressing

(b)(4) [Redacted]

(b)(4) Deficiencies [Redacted]

38



Trudell Medical International

(b)(4) Deficiencies

This addresses the issues identified in your RTA hold letter. Should you have any additional questions that I may be able to assist you with please contact me.

Best regards,

A handwritten signature in blue ink, appearing to read 'D. Fischer'.

Darryl Fischer, CQM
Associate Director, Global Regulatory Affairs
Trudell Medical International



Trudell Medical International

01 May 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
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Trudell Medical International

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Best regards,

A handwritten signature in blue ink that reads 'D Fischer'.

Darryl Fischer, CQM
Associate Director, Global Regulatory Affairs
Trudell Medical International

Section 11 - Device Description

Attachment 5 - Identification of Components

Document Title: Assembly Drawing

Document Number:





Trudell Medical International

FDA CDRH DMC

JUL 16 2014

Received

14 July 2014

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

K140919/52

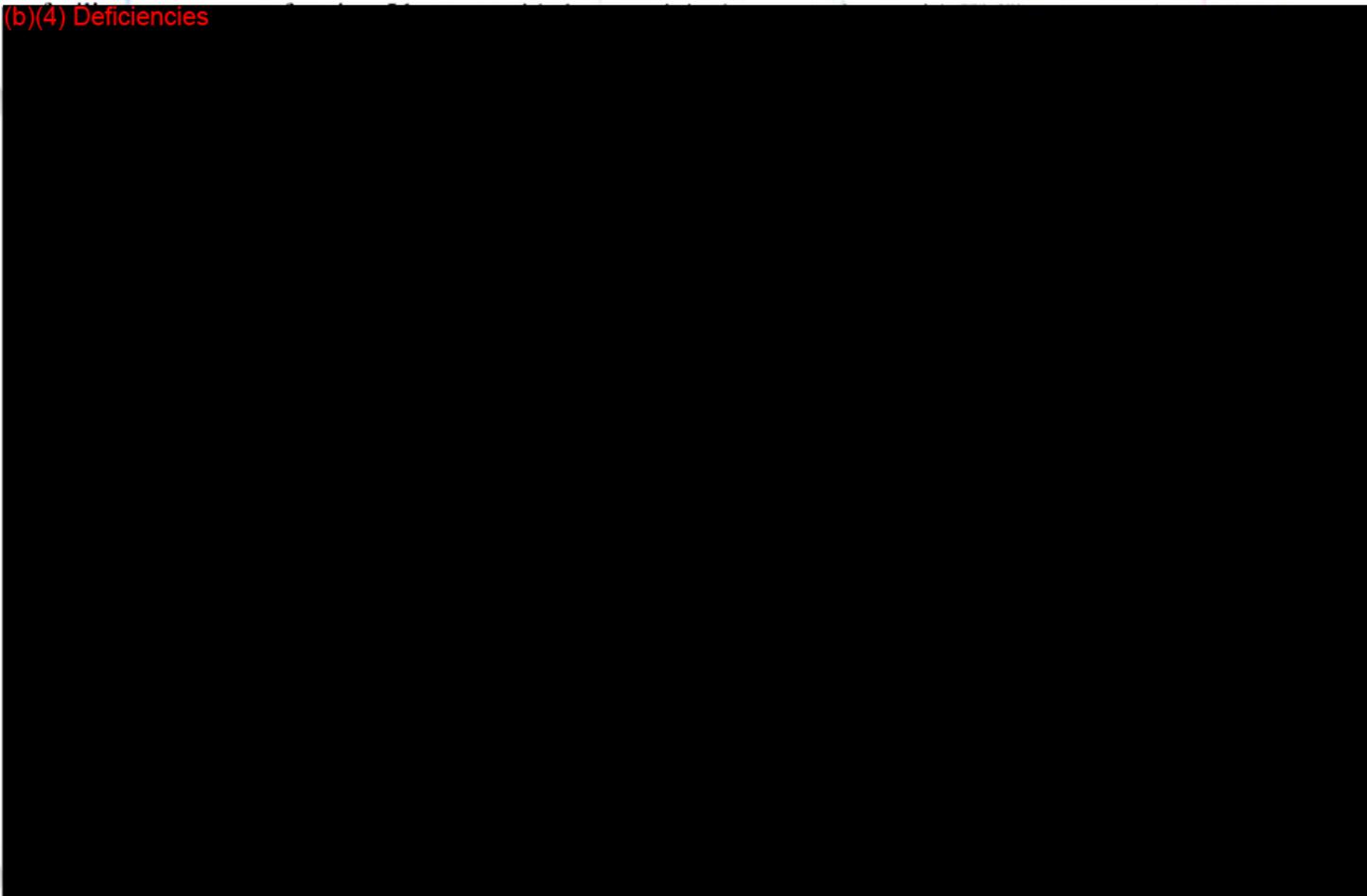
Subject: 510(k) K140919 Hold Letter Response

Attention: Deepika A. Lakhani, Ph.D.
Team Leader/ Lead Reviewer
Respiratory & Pulmonary Devices Branch

Dear Deepika,

I am providing the additional information you requested in your email hold letter dated 27 June 2014. To

(b)(4) Deficiencies



510(k) K140919 Hold Letter Response

Page: 1

725 Third Street, London, Ontario, CANADA, N5V 5G4 • Telephone: + 1(519) 455-7060 • Facsimile: + 1(519) 455-6329 • www.trudellmed.com

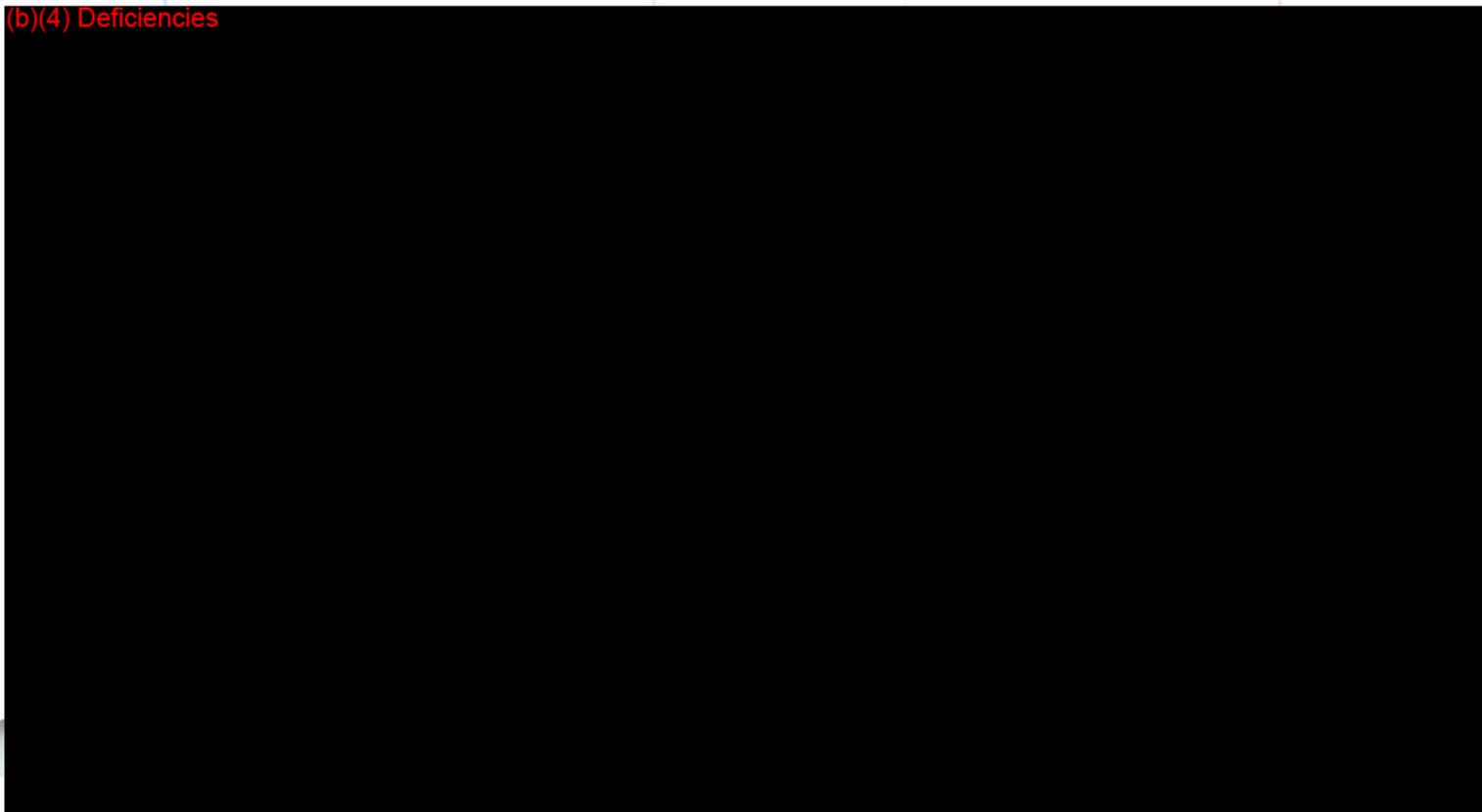
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

REGISTERED
ISO 13485
QUALITY SYSTEM



Trudell Medical International

(b)(4) Deficiencies



If you have any additional questions, please contact me at your earliest convenience.

Best regards,

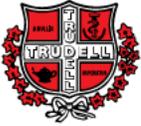
Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International
Ph: +1 519 455 7060, x2140
Fax: +1 519 455 6329
Email: dfischer@trudellmed.com

Premarket Notification 510(k)
RespiConnect Adapter

Trudell Medical International

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Trudell Medical International

14 July 2014

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

Subject: 510(k) K140919 Hold Letter Response

Attention: Deepika A. Lakhani, Ph.D.
Team Leader/ Lead Reviewer
Respiratory & Pulmonary Devices Branch

Dear Deepika,

I am providing the additional information you requested in your email hold letter dated 27 June 2014. To

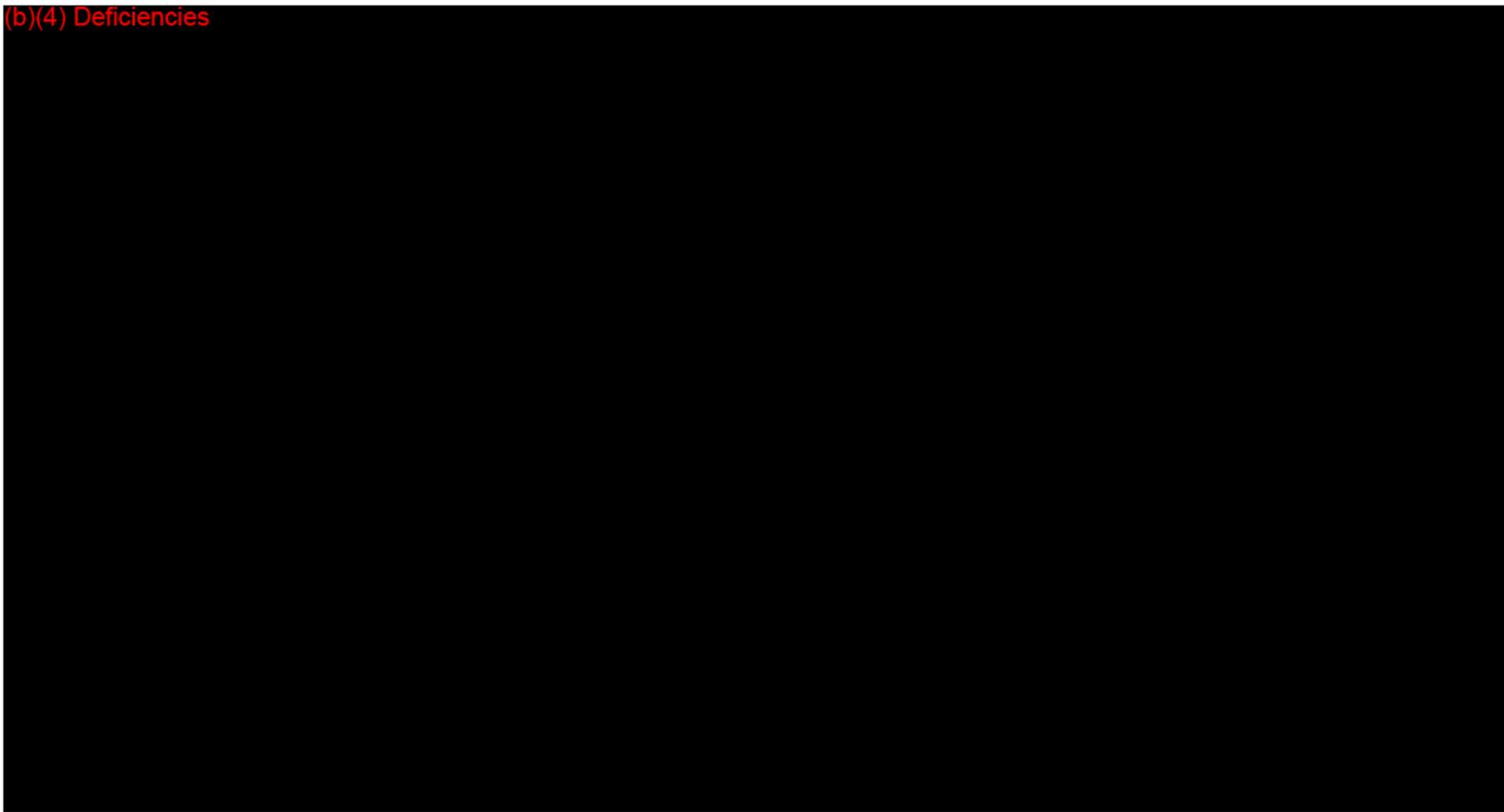
(b)(4) Deficiencies





Trudell Medical International

(b)(4) Deficiencies



If you have any additional questions, please contact me at your earliest convenience.

Best regards,

A handwritten signature in blue ink that reads 'D Fischer'.

Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International
Ph: +1 519 455 7060, x2140
Fax: +1 519 455 6329
Email: dfischer@trudellmed.com

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Performance Testing – Clinical	Section 20

Section 5 – 510(k) Summary

Prepared: 21 March 2014 / Amended 14 July 2014

510(k) Owner Trudell Medical International
725 Third Street
London, Ontario N5V 5G4
CANADA

Contact Person Darryl Fischer
Associate Director, Global Regulatory Affairs

Phone 1-519-455-7060 ext 2140
Fax 1-519-455-6329
e-mail dfischer@trudellmed.com

Device Name

Proprietary RespiConnect Adapter
Common/Classification Accessory to a nebulizer

Product Code CAF

Classification Regulation 868.5630

Predicate Device(s) 510(k) Number	Trade/Model Name	Manufacturer
K926301	Ace Cloud Enhancer	DHD Diemolding, Healthcare Division

Device Description

The RespiConnect Adapter is a single-patient use device intended to provide a self-sealing access port in a ventilator circuit to facilitate the administration of **Respimat**[™] Soft Mist inhaler medication to mechanically ventilated patients.

Intended Use

The RespiConnect Adapter is designed to be used with **RESPIMAT**[™] SOFT MIST INHALERS to facilitate the delivery of bronchodilator aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit. The intended use does not differ significantly from that of the predicate device detailed below. The predicate device below is designed to assist with the delivery of aerosolized medications from metered dose inhaler canisters to a mechanically ventilated patient.

Section 5 - 510(k) Summary

Ace Aerosol Cloud Enhancer, K926301

- Manufactured from plastic
- 22mm OD and ID fittings to accommodate 22 mm breathing circuit connections
- Used to administer aerosolized medication to a mechanically ventilated patient



Section 5 – 510(k) Summary

Technological Characteristic Comparison to Predicate Device

The table below presents some of the common device characteristics exhibited by the Class II device and the predicate device.

Common Device Characteristics		
Characteristic	 RespiConnect Adapter for Respimat™	 ACE Aerosol Cloud Enhancer K926301
Single Patient Use	Yes	Yes
For use in a ventilator circuit	Yes	Yes
Delivery of aerosol medication	Yes	Yes
Built in actuator	No	Yes
Sold non-sterile	Yes	Yes
22mm ISO fittings	Yes	Yes
Device Classification:	Class II – Accessory to a nebulizer	Class II – Accessory to a nebulizer

Relevant differences in the operating principles of the Adapter for Respimat™ and the predicate device;

- RespiConnect Adapter is used only with the Respimat™ Soft Mist Inhaler (SMI) device.
- RespiConnect Adapter has a self-sealing port to maintain circuit integrity once the Respimat™ device is removed. The ACE device must be capped to prevent circuit leakage if it remains in the circuit after use.
- RespiConnect Adapter remains in the circuit once installed, and is discarded with the circuit upon circuit change. The ACE device is not recommended to remain in the circuit once in place, and may be removed after each use.
- RespiConnect Adapter has a molded arrow to indicate direction of air flow. The ACE device is not labeled with the direction of air flow.

Section 5 – 510(k) Summary

- RespiConnect Adapter is not patient-orientation sensitive while medication is being delivered. The ACE device and pMDI is patient-orientation sensitive during aerosol delivery, as the pMDI must be oriented in the upright position during firing to ensure the labeled dosage of drug is properly delivered.

Non-Clinical Test Summary

Mechanical testing was conducted to characterize the operating parameters (leakage) of the RespiConnect Adapter device. The results (in Section 11, Attachment 4) demonstrate that the RespiConnect Adapter device performs satisfactorily, and does not raise any new safety or efficacy related issues.

There are no direct patient contacting components of the RespiConnect Adapter device. However, the materials of construction were tested for biocompatibility and do meet the requirements of ISO 10993-1:2009, Biological evaluation of medical devices.

Biological evaluation of the RespiConnect Adapter device was classified according to the requirements within ISO 10993-1 as follows;

- Category: Surface device
- Contact: Mucosal membranes
- Contact Duration: B – Prolonged Exposure (24hrs to 30 days)
- Evaluation Testing for Biological Effect
 - Cytotoxicity – according to ISO 10993-5
 - Sensitization – according to ISO 10993-10
 - Irritation or Intracutaneous Reactivity - according to ISO 10993-10

Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance Data.

Conclusions from Testing

The RespiConnect Adapter device has been compared against a currently marketed (predicate) device for the determination of substantial equivalency. The RespiConnect Adapter device and the predicate device share:

- common indications for use for mechanically ventilated patients
- usage environments
- both devices are single patient use
- both devices are sold non-sterile

The RespiConnect Adapter device raises no new issues regarding safety or efficacy.

Section 10 – Executive Summary

Device Description

The RespiConnect Adapter device is a single-patient use connector intended to provide a self-sealing access port in the inspiratory limb of a ventilator circuit to facilitate the administration of *RespiMat*™ Soft Mist inhaler medications to mechanically ventilated patients.

Intended Use

The RespiConnect Adapter is designed to be used with RESPIMAT™ SOFT MIST INHALERS to facilitate the delivery of bronchodilator aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

The above intended use does not differ significantly from that of the predicate devices detailed below. The predicate device is intended to be used in inspiratory limb of a ventilator circuit, for the purpose of administering aerosolized medication to a mechanically ventilated patient.

- ACE Aerosol Cloud Enhancer – K926301
- Manufactured from plastic
- 22mm OD and ID fittings to accommodate 22 mm breathing circuit connections



Section 10 – Executive Summary

Substantial Equivalence Comparison Table

The table below presents some of the common device characteristics exhibited by the Class II device and the predicate device.

Common Device Characteristics		
Characteristic	 RespiConnect Adapter	 ACE Aerosol Cloud Enhancer K926301
Single Patient Use	Yes	Yes
For use in a ventilator circuit	Yes	Yes
Delivery of aerosol medication	Yes	Yes
Built in actuator	No	Yes
22mm ISO Fittings	Yes	Yes
Device Classification	Class II – Accessory to a nebulizer	Class II – Accessory to a nebulizer

Relevant differences in the operating principles of the RespiConnect Adapter device and the predicate device(s);

- RespiConnect Adapter is used only with the Respimat™ Soft Mist Inhaler (SMI) device.
- RespiConnect Adapter has a self-sealing port to maintain circuit integrity once the Respimat™ device is removed. The ACE device must be capped to prevent circuit leakage if it remains in the circuit after use.
- RespiConnect Adapter remains in the circuit once installed, and is discarded with the circuit upon circuit change. The ACE device is not recommended to remain in the circuit once in place, and may be removed after each use.
- RespiConnect Adapter has a molded arrow to indicate direction of air flow. The ACE device is not labeled with the direction of air flow.
 RespiConnect Adapter is not patient-orientation sensitive while medication is being delivered. The ACE device and pMDI is patient-orientation sensitive during aerosol delivery, as the pMDI

Section 10 – Executive Summary

must be oriented in the upright position during firing to ensure the labeled dosage of drug is properly delivered.

Non-Clinical Test Summary

Mechanical testing was conducted to characterize the operating parameters (installation, leakage, etc.) of the RespiConnect Adapter device.

Mechanical testing consisted of the following;

- Simulated use
- Environmental limit testing (operating limits and environmental storage and transportation testing)
- Drop testing
- Connection leakage
- Fatigue and torsional testing
- Circuit resistance testing

The results (b)(4)

demonstrate that the RespiConnect Adapter performs in the same fashion to the predicate device, and does not raise any new safety or efficacy related issues.

There are no direct patient contacting components of the RespiConnect Adapter. However, the materials of construction do meet the requirements of ISO 10993-1:2009, Biological evaluation of medical devices.

Biological evaluation of RespiConnect Adapter device was classified according to the requirements within ISO 10993-1 as follows;

- Category: Surface device
- Contact: Mucosal membranes
- Contact Duration: B – Prolonged Exposure (24hrs to 30 days)
- Evaluation Testing for Biological Effect
 - Cytotoxicity – according to ISO 10993-5
 - Sensitization – according to ISO 10993-10
 - Irritation or Intracutaneous Reactivity - according to ISO 10993-10

Section 10 – Executive Summary

Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance Data.

Conclusions from Testing

The RespiConnect Adapter device has been evaluated against a currently marketed (predicate) device for the determination of substantial equivalency. The RespiConnect Adapter device and the predicate devices share:

- common indications for use
- usage environments
- both devices are single patient use
- non-sterile

The RespiConnect Adapter device raises no new issues regarding safety or efficacy.

Section 12 – Substantial Equivalence Discussion

Predicate Info (where available)

Predicate Device 510(k) Number	Trade Name	510(k) Holder
K926301	ACE Aerosol Cloud Enhancer	DHD Diemolding, Healthcare Division

Indications for use

The RespiConnect Adapter is designed to be used with RESPIMAT™ SOFT MIST INHALERS to facilitate the delivery of bronchodilator aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

Technology

The RespiConnect Adapter device is intended to be used by patients who are under the care or treatment of a health care provider or physician. The device is intended to be used to administer aerosolized medication from the Respimat™ Soft Mist Inhaler, prescribed by a physician or health care professional. The intended environments for use include hospitals and clinics.

The Intended Use and Indications of the RespiConnect Adapter device, as described in the labeling included in this submission in Section 13, are comparable to the predicate Class II device currently available on the market.

The RespiConnect Adapter device has been evaluated against the currently marketed (predicate) device for the determination of substantial equivalency. As outlined in the Substantial Equivalence Comparison Table found on page 3 of Section 10, the RespiConnect Adapter device and the predicate device share common indications for use, and usage environments. The devices are single patient use, non-sterile devices available by prescription.

The device characteristics of the RespiConnect Adapter have been evaluated against the predicate device cleared as a Class II device. The Substantial Equivalence Comparison Table found in Section 10, page 3, highlights the common device characteristics of the devices. As highlighted in the design control summary and supported by the risk analysis and verification

Section 12 – Substantial Equivalence Discussion

testing referenced in Section 11, the characteristics of the RespiConnect Adapter have been evaluated to ensure no new safety or effectiveness questions have been raised.

Summary

The information provided in this section demonstrates that the differences between the RespiConnect Adapter device and the predicate device raise no new issues of safety and effectiveness.

Section 13 – Proposed Labeling

The proposed labeling for the Adapter for Respimat™ is attached.

RespiConnect*

Adapter for RespiMat® Soft Mist® Inhaler



Trudell Medical International*

725 Third Street, London, Ontario, Canada N5V 5G4
 + 519-455-7060
 customerservice@trudellmed.com
 www.trudellmed.com



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 Biocity Nottingham, Pennyfoot Street,
 Nottingham, United Kingdom NG1 1GF

Canadian Hospital Distribution
 Trudell Medical Marketing Limited
 758 Third Street, London, ON, N5V 5J7

US Hospital Distribution
 Monaghan Medical Corporation
 5 Latour Avenue, Suite #1600, Plattsburgh, NY, USA 12901

REF 112501



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ENGLISH

The **RespiConnect*** adapter is designed to be used with RESPIMAT SOFT MIST INHALER formulations to facilitate the delivery of bronchodilator aerosol medication to mechanically ventilated patients. The single patient use adapter is intended to be left in the inspiratory limb of a 22 mm ventilator circuit.

The device is not intended to be cleaned between uses.

CAUTION: The **RespiConnect*** adapter is designed for use only in the inspiratory limb of a ventilator circuit. Use in any other part of the ventilator circuit is not recommended.

WARNING:

- SINGLE PATIENT USE
- CHANGE WITH CIRCUIT (MAX USE 30 DAYS)
- DO NOT STERILIZE
- DO NOT REUSE
- DO NOT USE NEAR STRONG MAGNETIC FIELD

DIMENSIONS

Overall Length	3.75 inches
Overall Height	2.25 inches
O.D. / I.D.	22 mm

Cascade Impactor Data for Combivent RESPIMAT® Soft Mist® Inhaler (SMI) with RespiConnect* Adapter

	Albuterol (Mean +/- 95% CI)	Ipratropium Bromide (Mean +/- 95% CI)
Total Delivered Dose (µg) from adapter	42.3 +/- 3.4	8.2 +/- 0.6
Respirable Fraction (0.4 – 4.7µm aerodynamic diameter) (%)	60.3 +/- 4.1	63.5 +/- 3.8
Respirable Particle Mass (0.4 – 4.7µm aerodynamic diameter) (µg)	25.5 +/- 2.9	5.2 +/- 0.4
Percentage Reduction in Respirable Particle Mass compared to the SMI alone (%)	48.7	49.0
Particle Fraction Greater than 4.7µm (%)	5.4 +/- 0.5	5.6 +/- 1.1
Particle Fraction Less than 1.1 µm (%)	57.8 +/- 4.3	55.0 +/- 4.1
MMAD	0.9	1.0

In-vitro data for reference only. N=5 devices. Cascade Impactor testing conducted at 28.3 lpm.



- Manufacturer



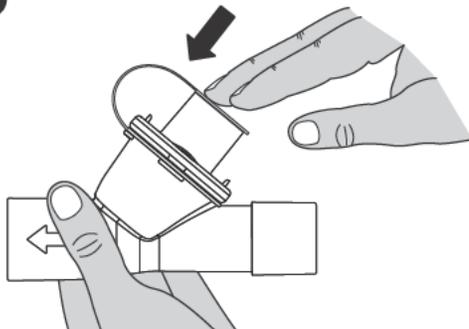
- Authorized European Representative



- Reference Number

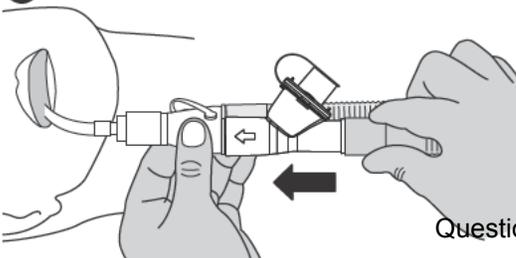
INSTALLATION INSTRUCTIONS

1

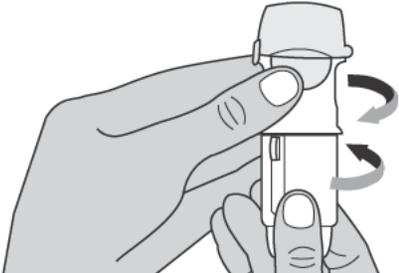
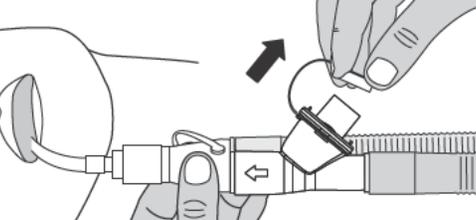
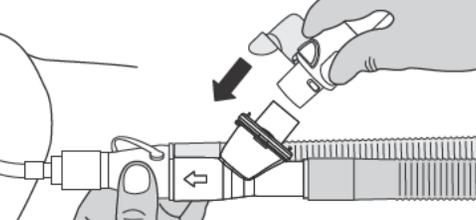
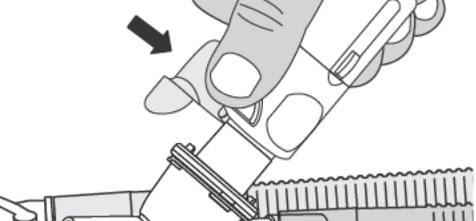
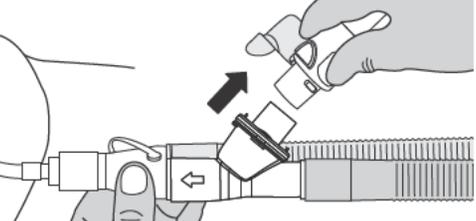
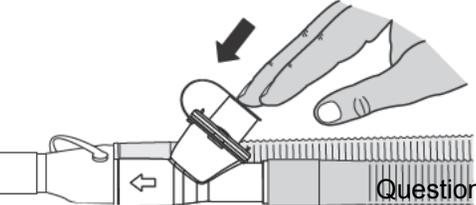


Remove the **RespiConnect*** adapter from its packaging and inspect for damage or missing components.
 Place cap on adapter ensuring it is firmly closed.
 The adapter can be used right out of package. Before use, ensure these instructions and the instructions supplied with the RESPIMAT® SOFT MIST® INHALER have been read and are kept available at all times.

2



Insert the **RespiConnect*** adapter into the inspiratory limb of the circuit as shown. Ensure the Wye Connector end is attached to the wye and that the arrow on the adapter is pointing towards the patient.
CAUTION: To avoid circuit disconnects, ensure connections are properly secured as intended.

	<p>Follow priming instructions for the RESPIMAT[®] SOFT MIST[®] INHALER as outlined in the instructions for use.</p> <p>The RESPIMAT[®] SOFT MIST[®] INHALER must be primed in an upright position (per the instructions supplied with the inhaler) before being inserted into the adapter.</p>	
	<p>Remove the cap from the adapter as shown.</p>	
	<p>Flip the cap on the RESPIMAT[®] SOFT MIST[®] INHALER until it snaps fully open.</p> <p>Fully insert the RESPIMAT[®] SOFT MIST[®] INHALER into the <i>RespiConnect</i>[®] adapter as shown.</p>	
	<p>At the onset of inspiration, press the dose release button on the RESPIMAT[®] SOFT MIST[®] INHALER.</p>	
	<p>After medication administration, remove the RESPIMAT[®] SOFT MIST[®] INHALER from the adapter.</p>	
	<p>Place cap on adapter ensuring it is firmly closed.</p> <p>The adapter is designed to be left in the ventilator circuit.</p> <p>If additional dose is required, repeat steps 1–6.</p>	

Section 15 – Biocompatibility

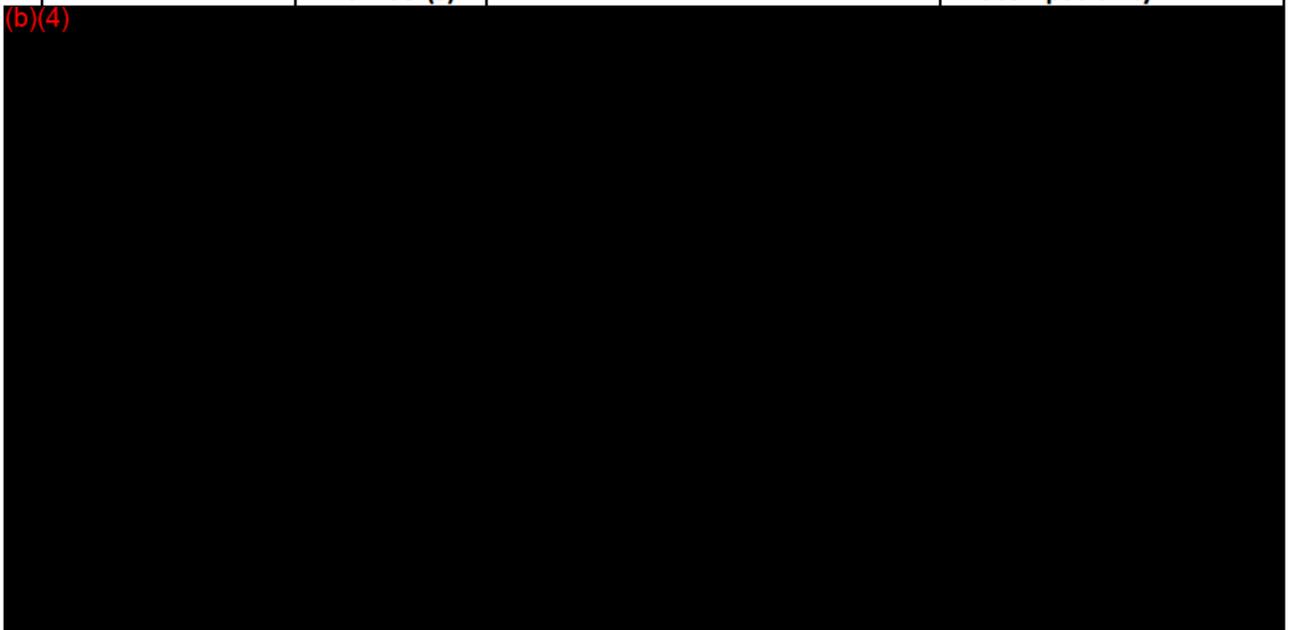
The plastic components of the RespiConnect Adapter have been evaluated in accordance with Blue Book Memo G95-1 “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” (May 1995). No components of the RespiConnect Adapter have direct patient contact.

A description of each component that has indirect (air-path) patient contact along with evidence of biocompatibility is provided in Table 1 of this section.

TABLE 1: In-direct Patient Contacting Components

Nature of Body Contact: (in accordance with section 5.2 of ISO 10993-1 Fourth edition 2009-10-15) Category: Surface device Contact: Mucosal membrane (indirect - air path)			
Contact Duration: (in accordance with section 5.3 of ISO 10993-1 Fourth edition 2009-10-15) Prolonged exposure (B) – cumulative single, multiple or repeated long-term use or contact is likely to exceed 24 h but not 30 d.			
Description	Part Number(s)	Material Identification	Evidence of Biocompatibility

(b)(4)

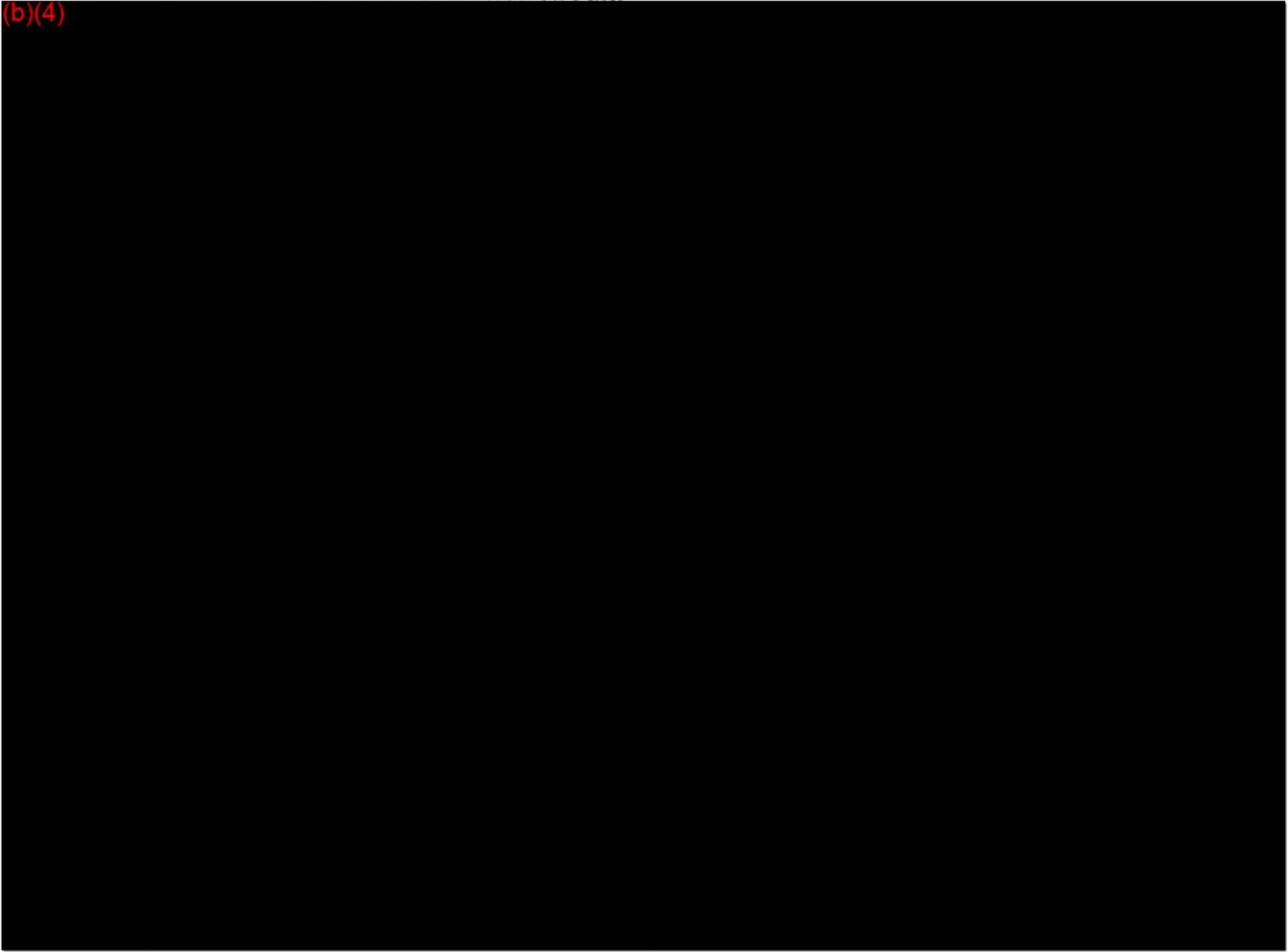


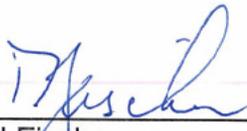
RespiConnect* Adapter 510(k) Notification K140919

Biocompatibility Certification

Three plastic components of the ***RespiConnect**** Adapter contact the gas path of patient while the device is in the ventilator circuit.

(b)(4)





Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International



Date