K131234

510(k) Summary

1. Date of Summary

October 10, 2013

2. 510(k) Applicant

Broncus Medical, Inc.
1400 N. Shoreline Blvd, Suite A8
Mountain View, California 94043
Phone: (650) 428-1600
FAX: (650) 428-1542

OCT 15 2013

Contact Person: Gary Kaplan
Phone: (650) 428-1600
Fax: (650) 428-1542
e-mail: gkaplan@broncus.com

3. Device Overview

Trade Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)

Common Name: Sheath and Dilation Balloon

Classification Name: Bronchoscope and Accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002
Olympus Guide Sheath	Olympus Medical Systems Corporation	K060243, cleared to market on June 23, 2006

5. Device Description

The LungPoint Tools are endoscopic tools used during bronchoscopy procedures. The LungPoint Sheath is designed to be used with a bronchoscope to provide a working

channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted lung tissue within the respiratory organs. The LungPoint Dilation Balloon is used to dilate tissue of the bronchial tree and may be inserted through the sheath or directly through the working channel of the bronchoscope. The bronchoscope is advanced to a predefined target following guidance of the LungPoint Software (previously cleared under 510(k) #K112051 to guide endoscopic tools or catheters in the lungs or to enable marker placement in soft lung tissue).

The materials used in the LungPoint Tools are commonly used medical grade materials and include platinum iridium markers.

The LungPoint Sheath has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

The LungPoint Dilation Balloon has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

6. Intended Use

The LungPoint Tools are endoscopic tools intended to be used with LungPoint Software guided bronchoscopes. The LungPoint Sheath is intended to be used as a working channel through which endoscopic tools may be introduced to targeted tissue. The LungPoint Dilation Balloon is intended to dilate tissue of the bronchial tree and may be inserted through the LungPoint Sheath or directly through the working channel of the bronchoscope. Not for pediatric use.

7. Comparison to Predicate Device

The LungPoint Tools are commonly used endoscopic tools with the same technological characteristics as the predicate devices. The indications for use of the LungPoint Tools for use with a bronchoscope guided by the LungPoint Software are all within the intended use of the predicate devices, which is to aid in reaching a target in the respiratory organ

either directly as is the case with the sheath or through dilating target tissue with the dilation balloon. The technological characteristics of the subject devices are the same as those of the predicate devices with the following exceptions

- LungPoint Balloon: balloon size and length, balloon burst pressure and balloon catheter length as outlined.

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	LungPoint Dilation Balloon
Balloon Size and Inflation (balloon pressure)	8mm @ 3 ATM 9mm @ 5.5 ATM 10mm @ 9 ATM	4mm @ 10 ATM
Catheter Length (cm)	155	143
Balloon Length (cm)	3.0	0.6
Rated Burst Pressure (atmospheres)	9	20

- LungPoint Sheath: stylet, catheter ID/OD and catheter length as outlined.

	Olympus Guide Sheath (K060243)	LungPoint Sheath
Stylet Provided	No	Yes - used to enhance pushability and to prevent airway mucosa entering sheath
Catheter ID/OD	2.1/2.7 mm	2.0/2.6 mm
Catheter Length	900 mm	975 mm

None of these differences raise new questions of safety and effectiveness. Performance of the subject devices has been verified by use of accepted methods.

8. Performance Data

The design and safety of the LungPoint Tools were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use. Testing included the following:

- Dimensional testing
- Joint/tensile test
- Simulated use
- Balloon fatigue/burst pressure
- Balloon deflation time
- Radiopacity.

All testing results met the pre-determined acceptance criteria that were established in the test protocols. Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

9. Safety and Effectiveness

The LungPoint Tools labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the devices. The biocompatibility assessment of all patient contacting materials was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices*. Specifically, cytotoxicity, sensitization, intracutaneous reactivity and systemic toxicity (acute) were tested. In addition, the devices are sterilized using e-beam sterilization.

10. Conclusion

Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

October 15, 2013

Broncus Medical, Inc.
(b)(4), (b)(6)
[redacted]

Re: K131234
Trade/Device Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 26, 2013
Received: August 27, 2013

Dear (b)(6) [redacted]

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131234

Device Name: LungPoint Tools - LungPoint Dilation Balloon and LungPoint Sheath

Indications for Use: The LungPoint Tools are endoscopic tools intended to be used with LungPoint Software guided bronchoscopes. The LungPoint Sheath is intended to be used as a working channel through which endoscopic tools may be introduced to targeted tissue. The LungPoint Dilation Balloon is intended to dilate tissue of the bronchial tree and may be inserted through the LungPoint Sheath or directly through the working channel of the bronchoscope. Not for pediatric use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ___ of ___

Srinivas Nandkumar -S

K131234

Broncus Medical, Inc.
1400 N. Shoreline Blvd.
Suite A8
Mountain View, CA 94043
www.broncus.com

(650) 428-1600
(650) 428-1542 fax

May 1, 2013

(b)(4) Third Party Information
(b)(6)
(b)(4) Third Party Information

Re: Traditional 510(k) Notification – LungPoint Tools

Dear (b)(6) (b)(4)

The electronic files (eCopy) are an exact duplicate of the paper copy included with this submission.

Should you have any questions, please contact me at (b)(4) Third Party Information or by e-mail at (b)(4) Third Party Information

Sincerely,

(b)(6)

Consulting Regulatory Affairs Director

K131234

Broncus Medical, Inc.
1400 N. Shoreline Blvd.
Suite A8
Mountain View, CA 94043
www.broncus.com

(650) 428-1600
(650) 428-1542

April 30, 2013

(b)(4) Third Party Information

(b)(4) Third Party Information

Re: Traditional 510(k) Notification – LungPoint Tools

Dear (b)(6)

The electronic files (eCopy) are an exact duplicate of the paper copy included with this submission.

Should you have any questions, please contact me at (b)(4) Third Party Information or by e-mail at (b)(4) Third Party Information

Sincerely,

(b)(6)

Consulting Regulatory Affairs Director

FDA Cover Letter

K131234

Date: April 30, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification 510(k) Electronic Copy:

Broncus Medical, Inc.
LungPoint Tools

To Whom It May Concern:

The electronic files (eCopy) are an exact duplicate of the paper copy included with this submission.

If you should have any questions regarding this submission please contact me at (b)(4) Third Party Information or email (b)(4) Third Party Information
Please fax any correspondence regarding this submission to (b)(4) Third Party Information (b)(4) Third Party Information

Sincerely,

(b)(6)

(b)(4) Third Party Information

18

(b)(4) Third Party Information

(b)(4)

(b)(4)

Date: April 29, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: New Device

B. Name and Address of the Third Party:

(b)(4) Third Party Information

C. Name and Address of the Manufacturer:

Broncus Technologies, Inc.
1400 N Shoreline Blvd, Suite A8
Mountain View, CA 94043

D. Device Name

Trade or Proprietary Name: LungPoint® Tools (LungPoint Sheath, LungPoint Dilation Balloon)

Classification Name: Bronchoscope and Accessories

Regulation Number: 21 CFR 874.4680

Recommendation: Substantially Equivalent

Date Submission was received by (b)(4) Third Party Information March 4, 2013

We have enclosed the following materials:

E. Authorization Letter from the applicant (MAL-F-0006).
F. Complete 510(k) application submitted by the applicant.
G. Documented review of the 510(k) application (RPP-F-0012, RPP-F-14 and all correspondence and documents related to the review).
H. Conflict of Interest Certification (RPP-F-0018)
I. Certification (RPP-F-0020)

If you should have any questions regarding this submission please contact me at (b)(4) Third Party Information or fax (b)(4) Third Party Information Please fax any correspondence regarding this submission to (b)(4) Third Party Information.

Sincerely,

(b)(6)

(b)(4)

Submission Certification

1. I certify that (b)(4) Third Party Information continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by the FDA;

2. In addition, I state that (b)(4) Third Party Information believes that statements made in the review are true and accurate to the best knowledge of (b)(4) Third Party Information

3. (b)(4) Third Party Information review is based on the 510(k) that is attached with the review; and

4. (b)(4) Third Party Information understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 33(q).

(b)(6)

(b)(6)

Date: 29 APR 2013

Conflict of Interest
Declaration and Certification
For the review of the 510(k) submission from

Applicant: **Broncus Technologies, Inc.**

Device Name or Model Name: **LungPoint Tools**

Initials

(b)(6)

I have read and understand (b)(4) Third Party Information Conflict of interest and Confidentiality Procedure (COI-S-0023), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

I have not been employed within the last twelve months by the firm who submitted the 510(k) for evaluation.

I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

I have not performed testing in connection with this specific device 510(k).

I understand that the Accredited Persons (AP) Program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.

I do not participate in the design, manufacture or distribution of any medical device.

I do not provide consultative services to any device manufacturer or distributor regarding specific device 510(k) or participate in the preparation of 510(k.

I have not performed a 510(k) review where I have a personal relationship with the sponsor or the application correspondent.

Signed: (b)(6)

Printed Nam

Date: 4 MAR 2013

Conflict of Interest
Declaration and Certification
For the review of the 510(k) submission from

Applicant: Broncus Medical, Inc.

Device Name or Model Name: LungPoint® Tools (LungPoint Sheath, LungPoint Dilation Balloon)

Initials

(b)(6)

I have read and understand (b)(4) Third Party Information Conflict of interest and Confidentiality Procedure (COI-S-0023), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

I have not been employed within the last twelve months by the firm who submitted the 510(k) for evaluation.

I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

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I do not provide consultative services to any device manufacturer or distributor regarding specific device 510(k) or participate in the preparation of 510(k.

I have not performed a 510(k) review where I have a personal relationship with the sponsor or the application correspondent.

Signed: (b)(6)

Printed Name:

Date: 3/5/13

Third Party Review
Reviewer Memorandum

Third Party Organization: (b)(4) Third Party Information

Signature: (b)(6)
Print Name:
Date: 4/29/13
Title: Reviewer

Signature: (b)(6)
Print Name:
Date: 4/29/13
Title: Program Supervisor

510(k) Applicant's Name: **Broncus Medical, Inc.**

Device Name: **LungPoint® Tools (LungPoint Sheath, LungPoint Dilation Balloon)**

Contact Person: (b)(6) **Regulatory Affairs Consultant**

(b)(4) Third Party Information

I. Purpose and Submission Summary:

The 510(k) holder **Broncus Medical, Inc.** is submitting a Traditional Premarket Notification to introduce the **LungPoint® Tools (LungPoint Sheath, LungPoint Dilation Balloon)**, which are new medical devices, into interstate commerce. The Broncus Medical, Inc. LungPoint Software with FlexNeedle (previously cleared under K112051) is not included in the scope of this submission as the previously cleared LungPoint Software with FlexNeedle is not being modified in any way to allow for the use of these LungPoint Tools.

During the review of the submission dated March 1, 2013 one round of deficiencies was issued on March 20, 2013. Additional information dated April 3, 2013 was provided to respond to the deficiencies. A second round of deficiencies was issued on April 19, 2013. Additional information dated April 22, 2013 was provided to respond to the deficiencies. All deficiencies have been adequately addressed.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use = **Prescription** Page Number: **Attachment 2 of Additional Information dated April 3, 2013**	X		
Truthful and Accuracy Statement Page Number: **Page 19 of the original submission**	X		
510(k) Summary Page Number: **Attachment 2 of Additional Information dated April 22, 2013**	X		
Standards Form (FDA Form 3654) Page Number: **Appendix I of the original submission and Attachment 3 of Additional Information dated April 22, 2013**	X		

III. Device Description

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

The submission and additional information describes the **LungPoint Sheath and LungPoint Dilation Balloon** as follows:

(b)(4) Third Party Information

Device Description

The updated device description is included in Attachment 6 of the Additional information dated April 3, 2013. The LungPoint Sheath and LungPoint Dilation Balloon are endoscopic tools, which are intended to be used as accessories to the Broncus Medical, Inc. LungPoint Software with FlexNeedle (previously cleared under K112051). The LungPoint Tools are described in more detail in the following subsections. The LungPoint Software (K112051) may be used with these tools or other commercially available tools. The LungPoint Tools have been specifically designed to be used with the LungPoint Software but can be used without the LungPoint Software, as well. The LungPoint Software with FlexNeedle (K112051) was not modified in any way to allow for the use of the LungPoint Tools and therefore is not included in the scope of this submission.

LungPoint Sheath

The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs. The sheath enables physicians to easily access targets and allows for multiple approaches to the preselected target. It allows for the repeated placement of endoscopic tools to a specified lesion(s) during one procedure. The sheath is provided with (b)(4), which is (b)(4)

The sheath (b)(4) is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools, (b)(4) section. Once placed, other endoscopic tools (b)(4) endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. (b)(4) tools. The LungPoint Sheath is provided as a sterile device for single use (b)(4) (b)(4). A detailed drawing of the sheath is provided in Appendix B of the original submission (a portion of which is inserted below).

(b)(4) Schematic Drawings

LungPoint Dilation Balloon

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or sheath and is used to dilate lung tissue. The balloon may be used (b)(4)

(b)(4) as determined by the physician performing the bronchoscopy. The LungPoint Dilation Balloon (b)(4), and is a sterile device for single use.

Balloon Size (OD x length)	Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/ working length
4mm x 6mm	10 atm	1mm	1430mm/975mm

When inflated at (b)(4) the balloon dimensions are (b)(4)). A detailed drawing of the LungPoint Dilation Balloon is provided in Appendix B of the original submission (a portion of which is inserted below).

(b)(4) Schematic Drawings

Device Specifications

The following tables (extracted from Section 11 Device Description) outline the proposed **LungPoint Sheath and LungPoint Dilation Balloon** device performance characteristics and specifications.

LungPoint Sheath Specifications

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
Dimensional Testing	To verify that the devices meet the product specification of the following Dimensional Tests: Inner diameter Outside diameter Sheath length Stylet tip diameter Stylet length	NA – all criteria are per the product specifications	(b)(4)
Joints/ Tensile Test	To verify that the joints of the sheath and stylet meet the tensile requirements of ISO 10555 and EN 1618	Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995	

Performance Specification	Objective	Applicable Standards	Acceptance Criteria
Simulated Use	To verify that the sheath (b)(4) meet product specifications regarding use in a bronchoscope after repeated device insertions which constitute normal (b)(4)	NA – validated test fixture	(b)(4)
Radiopacity	(b)(4)	NA	

LungPoint Dilation Balloon Specifications

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
Dimensional Testing	To verify that the devices meet the product specification of the following Dimensional Tests: (b)(4)	NA – all criteria are per the product specifications	(b)(4)
Joints/ Tensile Test	To verify that the joints of the dilation balloon meet the tensile requirements of ISO 10555 and EN 1618	Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995	

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
Simulated Use	To verify that the balloon meets product specifications regarding use in a bronchoscope after repeated device insertions which constitute normal use, in a test fixture (b)(4) .	NA – validated test fixture	(b)(4)
Balloon burst pressure	To verify fatigue capabilities of the balloon and that balloon will not burst at or below maximum recommended burst pressure	NA	
Radiopacity	Verify that marker bands are visible under fluoroscopy (b)(4)	NA	

List of Materials

The following tables outline the lists of components and the patient contacting materials for the **LungPoint Sheath and LungPoint Dilation Balloon**.

LungPoint Sheath

Material Use	Material Description	Common Name
(b)(4)		

(b)(4) Manufacturing Information

[redacted]

LungPoint Dilation Balloon

(b)(4) Manufacturing Information

[redacted]

(b)(4) Third Party Information

[redacted]

(b)(4) Third Party Information

[redacted]

IV. Indications for Use

The proposed Indications for Use for the new device **LungPoint Tools - LungPoint Sheath and LungPoint Dilation Balloon** are as follows:

> The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

The Indications for Use listed above for the **LungPoint Tools - LungPoint Sheath and LungPoint Dilation Balloon** are the same as the Indications for Use stated in the Indications for Use form, the 510(k) Summary and the Instructions for Use.

V. Predicate Device Comparison

The updated Section 12 in Attachment 7 of the Additional Information dated April 3, 2013 and the responses in the Additional Information dated April 22, 2013 provide comparisons between the **LungPoint Sheath and LungPoint Dilation Balloon** submitted in this 510(k) and the predicate devices outlined below.

Predicate Device Trade Name	510(k) Submitter	510(k) Number	Reg # / Product Code
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System (with FlexNeedle)	Broncus Technologies, Inc*	K112051, cleared to market on October 12, 2011 (and K093423, K091160 and K090095, by reference)	892.2050 / LLZ Picture Archiving and Communications System
inReach System	SuperDimension	K110093, cleared to market on February 11, 2011 (and K071473, K092365 and K102604, by reference)	892.1750 / JAK Computed Tomography X-Ray System
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002	874.4680 / KTI Bronchoscope and Accessories

*NOTE: Broncus Technologies, Inc changed their name to Broncus Medical, Inc in June 2012.

The LungPoint Tools (proposed regulation # 874.4680 and product code EOQ for Bronchoscope and Accessories), which are designed to be used as accessories to the LungPoint Software System that was cleared to market under K112051, are commonly used endoscopic tools. They are similar to other commercially available endoscopic tools but were designed to be used as accessories to the LungPoint Software.

(b)(4)

Similarities and differences among these devices are outlined in the following comparison tables.

Comparison Table LungPoint Tools for use with LungPoint Software

	i Logic inReach System Components and Tools (K110093)	**LungPoint Software with FlexNeedle (K112051) and LungPoint Tools (new device)**
Intended Use (General Purpose of Device – encompasses indication)	Enable the diagnosis and the treatment of lung cancer. The inReach Tools and Components are designed to enable physicians to reach distant lung lesions in a minimally invasive manner. They are specifically designed for use with the i·Logic System. Endoscopic tools and components include biopsy forceps, cytology brushes, aspiration needles, locatable guide, guide catheter etc.	Enable the diagnosis and the treatment of lung cancer. The LungPoint Tools are specifically designed for use with the LungPoint Software. Endoscopic tools include FlexNeedle aspiration needle (previously cleared under K112051), sheath and dilation balloon (new devices).
Indications for Use for Software	The indications for use of the inReach System: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.	The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner. The LungPoint Tools are being cleared for use with the LungPoint Software System. The indications for use of the LungPoint Software: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.
Radiopaque Markers	Yes	Yes
Delivery Approach	Visual (via bronchoscope) and/or Fluoroscopy	Visual (via bronchoscope) and/or Fluoroscopy
Delivered Through	Flexible bronchoscope with minimum working channel of (b) mm	Flexible bronchoscope with minimum working channel of (b) mm
Single Use	Yes	Yes
Sterile	Yes	Yes

Comparison Table LungPoint Sheath

	I-Logic inReach Extended Working Channel (K110093)	LungPoint Sheath (new device)
Indications for Use for Tools	There are no separate indications for use of the inReach System Tools and Components as they fall under the indications for the software: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.	The proposed indications for use for the LungPoint Tools are: The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.
Stylet Provided	(b)(4)	
Stylet Use		
Catheter ID/OD	2.0/2.6 cm	2.0/2.6 cm
Catheter Length	975 mm	975 mm
Tensile Strength	Complies with ISO 10555 as it is the industry standard (assumed)	Complies with ISO 10555

Comparison Table LungPoint Dilation Balloon

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	LungPoint Dilation Balloon (new device)
Indications for Use for Tools	The cleared indications for use for the CRE Pulmonary Balloon Dilatation Catheter are: The CRE Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.	The proposed indications for use for the LungPoint Tools are: The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.
Balloon Size and Inflation (balloon pressure)	(b)(4)	
Catheter Length		
Inflation Port		
Balloon Length		
Rated Burst Pressure		
Tensile Strength	Complies with ISO 10555 as it is the industry standard (assumed)	Complies with ISO 10555

The following comparison information has been summarized from the submission and includes a comparison of the similarities and differences in the intended use/indications for use and the device specifications.

The **LungPoint Sheath and LungPoint Dilation Balloon** has the following similarities to the predicate devices:

- Same intended use (LungPoint Software with FlexNeedle plus LungPoint Sheath and LungPoint Dilation Balloon vs. inReach System Tools and Components)
- Same software indications for use (LungPoint Software with FlexNeedle vs. inReach System)
- Similar tools indications for use (LungPoint Sheath vs. inReach System Tools and Components)
- Similar tools indications for use (LungPoint Dilation Balloon vs. CRE Pulmonary Balloon Dilatation Catheter)
- Same target tissues (will reach distant lung lesions)
- Same operating principle (minimally invasive access through bronchoscopes)
- Similar fundamental scientific technology (sheaths and dilation balloon catheters utilize similar technologies, dimensions, and performance characteristics)
- Same dimensions for sheath/stylet tools (LungPoint Sheath vs. inReach System Tools and Components)
- Same sterile condition and intended for single use only

The differences between the **LungPoint Sheath and LungPoint Dilation Balloon** and the predicate devices are as follows:

(b)(4)

Several Design Differences

The development and design inputs of the proposed new device design were based on customer requirements in accordance with Broncus Medical's Design Control SOP. Both the new and predicate devices use the same method of action of dilating target tissue (b)(4) (b)(4) The key questions of safety and effectiveness relating to the dilation of target tissue in the lung are (b)(4)

(b)(4)

(b)(4)

require more pressure to burst. The process of inflation/deflation of the LungPoint Dilation Balloon remains the same.

(b)(4) Third Party Information

(b)(4)

These differences in designs were supported by the full list of design verification testing conducted to demonstrate the new device complies with the Performance Specification Tables in the **Device Specifications** section on page 4 of this Review Memorandum. These test results including (b)(4) (b) were reviewed and found acceptable. Refer to **Section XI Performance Testing Bench** of this Review Memorandum for a summary of this design verification testing. These design differences have been adequately addressed.

Summary

Although there are some differences between the new devices and the predicate devices, these changes would not be expected to pose any additional or new risks beyond the predicate device designs since they performed equivalently in the biocompatibility testing and bench performance testing. The LungPoint Sheath and LungPoint Dilation Balloon met all the predetermined acceptance criteria of design verification as specified by applicable standards and FDA guidance. Therefore, these differences in the new device do not raise any new issues of safety and effectiveness, and the new LungPoint Sheath and LungPoint Dilation Balloon are equivalent in design and technological characteristics to the predicate devices.

Intended Use/Indications for Use

The proposed Indications for Use for the new device **LungPoint Tools - LungPoint Sheath and LungPoint Dilation Balloon** are as follows:

> The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

The proposed indications for use for the new device are very similar to the cleared indications (b)(4)

> Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

The proposed indications for use for the new device are very similar to the cleared indications for the CRE Pulmonary Balloon Dilatation Catheter predicate device (K023337) which are as follows:

> The CRE Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.

The **LungPoint Sheath and LungPoint Dilation Balloon** have the same indications for use as the predicate devices combined.

Principle of Operation / Technological Characteristics

The **LungPoint Sheath and LungPoint Dilation Balloon** employ the same principles of operation and similar design and construction as the predicate devices.

Design / Materials / Specifications

The similarities and differences in physical designs and specifications between the new devices **LungPoint Sheath and LungPoint Dilation Balloon** and the predicate devices were outlined in the predicate device comparison tables above. Refer to **Section XI Performance Testing Bench** for a summary of the verification activities completed to demonstrate the design outputs of the new device met the design inputs and user need requirements. Since there are no significant differences in designs between the new devices and the predicate devices, there would not be any additional or new risks expected beyond the predicate device designs since they performed equivalently in the bench performance testing outlined below.

Performance

The new devices **LungPoint Sheath and LungPoint Dilation Balloon** submitted in this 510(k) and the predicate devices have very similar performance characteristics. To support the new device's design verification, the following tables outline the lists of performance testing that was completed using the new LungPoint Sheath and LungPoint Dilation Balloon. All LungPoint Sheath and LungPoint Dilation Balloon samples used for testing of each product attribute were representative of finished products. The new LungPoint Sheath and LungPoint Dilation Balloon met all of the design verification specifications/requirements as outlined in the Performance Specification Tables in the **Device Specifications** section on page 4 of this Review Memorandum. Section 18 and the test reports in Appendices H1 through H4 in the submission include summaries with detailed descriptions of the bench test methods, acceptance criteria, and conclusions demonstrating compliance with the product specifications. The passing results are summarized below. Refer to **Section XI Performance Testing Bench** for a more detailed summary of the verification activities completed.

(b)(4)

[redacted]

outlines the performance testing recommended for (b)(4) [redacted] e sponsor's rationale for their applicability to the LungPoint Tools. Note that the significance of each requirement in the following table has been modified from the FDA Guidance to remove (b)(4) [redacted]

Accredited Person
SE Documentation

Requirements	Applicable? Yes/No	Rationale/Testing Conducted
(b)(4)		

(b)(4) Third Party Information

(b)(4) Third Party Information

Requirements	Applicable? Yes/No	Rationale/Testing Conducted
(b)(4)		

The following tests were performed on **LungPoint Sheath** devices that were subjected to the (b)(4), where applicable. All testing results met the pre-determined acceptance criteria that were established in the test protocols. The following table summarizes the performance testing conducted to support the LungPoint Sheath performance. A detailed discussion is included in the test reports in Appendices H1 through H3 in the original submission.

LungPoint Sheath Specifications and Performance Testing Results

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)	Results
(b)(4)				Pass
				Pass
				Pass
				Pass

The following tests were performed on **LungPoint Dilation Balloon** devices that were (b)(4), where applicable. All testing results met the pre-determined acceptance criteria that were established in the test protocols. The following table summarizes the performance testing conducted to support the LungPoint Dilation Balloon performance. A detailed discussion is included in the test reports in Appendices H1 through H4 in the original submission.

LungPoint Dilation Balloon Specifications and Performance Testing Results

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)	Results
(b)(4)				**Pass**
				Pass
				Pass
				Pass

(b)(4)

The design verification performance test summary above demonstrates the **LungPoint Sheath and LungPoint Dilation Balloon** met all the predetermined product specifications and acceptance criteria as specified by the test protocols and/or customer inputs. Similar performance testing methods for intravascular catheter systems are outlined in the FDA Guidance entitled Guidance for Industry and FDA Staff - Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems and FDA recognized ISO 10555-1 standard. Therefore, the physical designs, materials, and specifications for the LungPoint Sheath and LungPoint Dilation Balloon have been tested by appropriate methods and no new issues of safety and effectiveness are raised based on the performance characteristics and testing of the new device.

Conclusion

The **LungPoint Sheath and LungPoint Dilation Balloon** have the same indications for use and the same intended use as the predicate devices. The LungPoint Sheath and LungPoint Dilation Balloon are equivalent in design and technological characteristics to the predicate devices. Based on the comparisons with the predicate devices above and the safety and performance testing results provided in the submission, the LungPoint Sheath and LungPoint Dilation Balloon do not raise new questions of safety or effectiveness.

VI. Labeling

The updated proposed Instructions for Use for the **LungPoint Sheath and LungPoint Dilation Balloon** device are provided in Attachment 3 of the Additional Information dated April 3, 2013 and Attachment 1 of the Additional Information dated April 22, 2013, respectively. The updated proposed pouch labels are provided in Attachment 8 of the Additional Information dated April 3, 2013. The updated LungPoint Software with Endoscopic Tools Instructions for Use Addendum DRAFT is provided in Attachment 9 of the Additional Information dated April 3, 2013.

The proposed labels include all the relevant warnings and cautions to the user as were in the predicate device labels such as Rx only, see packaging insert for explanation of symbols, for single use, sterilized using radiation, sterility guaranteed if package unopened and undamaged. (b)(4)

The Instructions for Use for this prescription only device includes all of the relevant warnings and precautions as the predicate device, such as, the prescription only caution statement, sterilization information including do not re-use or resterilize, for single patient use only statement, follow the bronchoscope manufacturer's Instructions for Use, the statement that this device should only be used by trained physicians, inspection of the device and package seal for any damage prior to use, the possible complications, (b)(4)

(b)(4) The Instructions for Use includes the same indications for use as the Indications for Use form. The Device Description includes product configuration and dimensions table that outlines key information such as **LungPoint Sheath** (b)(4) **, LungPoint Dilation Balloon** (b)(4) s of the devices. The Contraindications section states there are no known contraindications. The Preparation for Use, Operating Instructions, and Storage sections provide detailed step by step directions to assist the user in proper use of the device along with any relevant warning or precautionary notes. The last note in the **LungPoint Dilation Balloon** Operating Instructions states, "NOTE: The (b)(4)

The Graphic Symbol Legend is included on the last page to explain all symbols used on the labels. No other specific claims are made which would raise questions of safety and effectiveness.

VII. Sterilization/Shelf Life/Reuse

The **LungPoint Sheath and LungPoint Dilation Balloon** device is provided sterile to the user and is labeled for single use only. The sterilization information included in Section 14 of the submission and the Additional Information dated April 3, 2013 is summarized in the table below.

	YES	NO
1. Sterilant:	X	
a. **Sterilization method** description (e.g., Steam, EtO, Radiation): **Radiation (electron beam (E-beam))**	X	
b. **Dose**, for radiation (e.g., 25 – 50 kGy): (b)(4)	X	
c. **Sterilant residuals** remaining on the device: **N/A** For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);		X
2. A description of the Validation Method for the sterilization cycle (not data): ISO 11137-1 :2006 and ISO 11137-2 :2012 using the method VDmax (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	X	
3. Sterility assurance level (SAL): 10^{-6} (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	X	
4. Is it labeled "Pyrogen Free"? No		X
If so, a description of the method: **N/A** (e.g., LAL (*Limulus* Amebocyte Lysate test))		X

	YES	NO
5. A description of the packaging (not including package integrity test data): **Each product is placed in** (b)(4) (b)(4) (b)(4) .	X	

Shelf Life

The **LungPoint Sheath and LungPoint Dilation Balloon** will have a shelf-life (b)(4). The data to support the shelf-life will be available prior to commercialization. The shelf life verification testing protocol includes (b)(4)

Shelf-life will be extended to up (b)(4) of representative samples (b)(4) lines (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) on the packaging. Testing of the **LungPoint Sheath and LungPoint Dilation Balloon** includes the following performance tests:

- Dimensional Testing (b)(4)
- Simulated Use Testing (b)(4))
- Tensile (b b)(4) (b)(4) testing (b)(4))
- Balloon Fatigue and Burst Testing (b)(4)).

The same performance tests will be conducted at each time interval as were tested for the design verification testing except for (b)(4) which is not affected by aging.

The submission includes all required details related to packaging, sterilization, and expiration dating. The device is intended for single use only.

VIII. Biocompatibility

The following tables outline the lists of components and the patient contacting materials for the **LungPoint Sheath and LungPoint Dilation Balloon**. For details on the colorants used in the **LungPoint Sheath**, refer back to the **List of Materials** Section starting on page 7 of this Review Memorandum. The colorant information provided by the sponsor was reviewed and found acceptable.

LungPoint Sheath

Material Use	Material Description	Common Name	Patient contact
(b)(4)			

LungPoint Dilation Balloon

Material Use	Material Description	Trade Name	Patient contact
(b)(4)			

Biocompatibility testing in accordance with FDA Blue Book Memo G95-1 and ISO 10993-1:2009 was required. The LungPoint Sheath and LungPoint Dilation Balloon are categorized as external communicating devices that will have limited exposure to mucosal membranes and lung tissues for <24 hr. Devices of this classification typically require the following tests: Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, and Acute Systemic Toxicity. The following tests were conducted: Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, and Acute Systemic Toxicity.

Biocompatibility studies were conducted by (b)(4) (b)(4) following ISO 10993 to ensure that the materials are safe to use for their intended duration and purpose. All parts coming into

direct or indirect contact with the patient (as outlined in the tables above) were tested. All testing was performed on finished, post-sterilized test articles. Test articles were extracted per the requirements in ISO 10993-12 (b)(4) (b)(4)

All testing was completed in accordance with GLP regulations. Refer to the complete Biocompatibility Reports provided in Appendix G of the original submission. All reports were reviewed and found acceptable. Biocompatibility results summarized below and in these reports show that both devices meet all test requirements.

Test Name	Test Description	Results
Cytotoxicity	ISO 10993-5: In Vitro Cytotoxicity (L929 MEM Elution)	Pass (non-cytotoxic)
Sensitization	ISO 10993-10: Sensitization	Pass (non-sensitizing)
Intracutaneous Reactivity	ISO 10993-10: Irritation and Delayed-Type Hypersensitivity (Injection)	Pass (non-irritant)
Systemic Toxicity (Acute)	ISO 10993-11: Systemic Toxicity (Acute)	Pass (non-toxic)

The results of all biocompatibility testing were reviewed and found acceptable; no additional biocompatibility testing is required for the **LungPoint Sheath and LungPoint Dilation Balloon**. The LungPoint Sheath and LungPoint Dilation Balloon are considered safe and biocompatible for their intended use. No new questions related to safety and effectiveness are raised by the biocompatibility testing.

IX. Software

The **LungPoint Tools (LungPoint Sheath and LungPoint Dilation Balloon)** do not employ software. The Broncus Medical, Inc. LungPoint Software with FlexNeedle (previously cleared under K112051) is not included in the scope of this submission and the previously cleared LungPoint Software with FlexNeedle is not being modified to allow for the use of these LungPoint Tools. The existing risk analysis for the LungPoint Software was reviewed to assess whether guidance of the LungPoint Sheath and LungPoint Dilation Balloon adds any new hazards. No new risks were identified as the use of endoscopic tools, like the sheath and dilation balloon, is inherent to the design and intended use of the existing LungPoint Software. Additionally, no new verification and validation testing was performed as the LungPoint Software was not modified in any way to allow for the use of the LungPoint Tools.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device is not electrically powered.

XI. Performance Testing – Bench

The new devices **LungPoint Sheath and LungPoint Dilation Balloon** submitted in this 510(k) and the predicate devices have very similar performance characteristics. To support the new device's design verification, the following tables outline the lists of performance testing that was completed using the new LungPoint Sheath and LungPoint Dilation Balloon. All LungPoint Sheath and LungPoint Dilation Balloon samples used for testing of each product attribute were

representative of finished products. The new LungPoint Sheath and LungPoint Dilation Balloon met all of the design verification specifications/requirements as outlined in the Performance Specification Tables in the **Device Specifications** section on page 4 of this Review Memorandum. Section 18 and the test reports in Appendices H1 through H4 in the submission include summaries with detailed descriptions of the bench test methods, acceptance criteria, and conclusions demonstrating compliance with the product specifications. The passing results are summarized below.

Refer to **Section V Predicate Device Comparison** for a more detailed summary of the design verification test methods that were utilized compared to the FDA Guidance entitled Guidance for Industry and FDA Staff - Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems (beginning on page 13 of this Review Memorandum).

The following tests were performed on **LungPoint Sheath** devices that were subjected to the required (b)(4), where applicable. All testing results met the pre-determined acceptance criteria that were established in the test protocols. The following table summarizes the performance testing conducted to support the LungPoint Sheath performance. All samples sizes for this table were (b)(4). A detailed discussion is included in the test reports in Appendices H1 through H3 in the original submission.

LungPoint Sheath Design Verification Testing Summary

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)	Results
Dimensional Testing	To verify that the devices meet the product specification of the following Dimensional Tests: Inner diameter Outside diameter (b)(4)	NA – all criteria are per the product specifications	(b)(4)	
Joints/ Tensile Test	To verify that the joints of the sheath and stylet meet the tensile requirements of ISO 10555 and EN 1618	Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995		

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)	Results
Simulated Use	(b)(4)	NA – validated test fixture	(b)(4)	
Radiopacity	(b)(4)	NA		

The following tests were performed on **LungPoint Dilation Balloon** devices that were subjected to the required (b)(4), where applicable. All testing results met the pre-determined acceptance criteria that were established in the test protocols. The following table summarizes the performance testing conducted to support the LungPoint Dilation Balloon performance. All samples sizes for this table (b)(4) A detailed discussion is included in the test reports in Appendices H1 through H4 in the original submission.

LungPoint Dilation Balloon Design Verification Testing Summary

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)	Results
Dimensional Testing	(b)(4)	NA – all criteria are per the product specifications	(b)(4)	
Joints/ Tensile Test		Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995		
Simulated Use		NA – validated test fixture		

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)	Results
Balloon burst pressure	(b)(4)	NA	(b)(4)	
Radiopacity	(b)(4) (b)(4) n.	NA		

The design verification performance test summary above demonstrates the **LungPoint Sheath and LungPoint Dilation Balloon** met all the predetermined product specifications and acceptance criteria as specified by the test protocols and/or customer inputs. Similar performance testing methods for intravascular catheter systems are outlined in the FDA Guidance entitled Guidance for Industry and FDA Staff - Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems and FDA recognized ISO 10555-1 standard. Therefore, the physical designs, materials, and specifications for the LungPoint Sheath and LungPoint Dilation Balloon have been tested by appropriate methods and no new issues of safety and effectiveness are raised based on the performance characteristics and testing of the new device.

Conclusion: The bench test results support the conclusion that the performance of the **LungPoint Sheath and LungPoint Dilation Balloon** is similar to the performance of the predicate devices. No new questions of safety and effectiveness are raised.

XII. Performance Testing – Animal

This submission does not include animal testing or data.

XIII. Performance Testing – Clinical

This submission does not include human clinical testing or data.

XIV. Substantial Equivalence Discussion

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

Note: Document the decision path by marking the arrows followed on the FDA flowchart.

Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

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

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

   The submission includes the descriptive characteristics but the performance testing is needed to support substantial equivalence and demonstrate the similarities between the new devices and the predicate devices.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods cannot be used:

8. Explain what performance data is needed:

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

As the reviewer of this submission I have reviewed the instructions for use, the submitter's description of the devices and compared this information against the information concerning the predicate devices that was provided by the submitter. The specifications for the predicate devices and the new devices have been compared. They are very similar. The predicate device comparison tables demonstrate the similarities and differences between the new devices and predicate devices. The submission includes performance and biocompatibility testing which demonstrates the new devices and the predicate devices possess similar performance characteristics. The labeling included in the submission was reviewed and found to be very similar to the predicate labeling. There are no new questions of safety and effectiveness raised during this review.

Based upon the above summary, a substantially equivalent decision is recommended.

XV. Deficiencies

During the review of the submission dated March 1, 2013 one round of deficiencies was issued on March 20, 2013. Additional information dated April 3, 2013 was provided to respond to the deficiencies. A second round of deficiencies was issued on April 19, 2013. Additional information dated April 22, 2013 was provided to respond to the deficiencies. All deficiencies have been adequately addressed.

XVI. Contact History

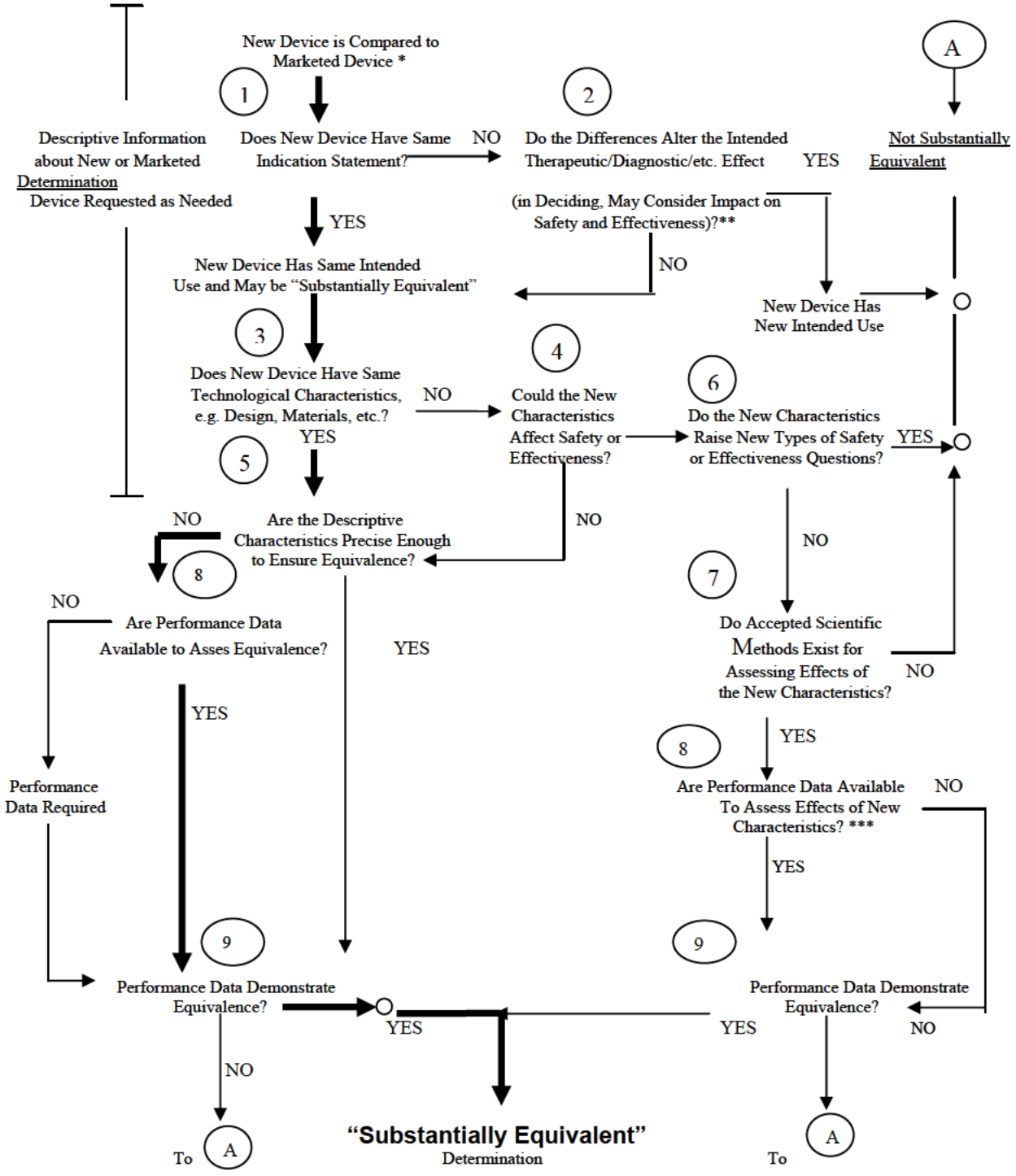
All correspondence is included in the submission.

XVII. Recommendation

Regulation Number:	**21 CFR 874.4680**
Regulation Name:	**Bronchoscope and Accessories**
Regulatory Class:	**II**
Product Code:	**EOQ**

LungPoint Tools (LungPoint Sheath, LungPoint Dilation Balloon)

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



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

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

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

This page represents the additional information provided by the sponsor.

Please see the enclosed Sponsor eCopy in

Folder labeled as

VOL_003_Response to 19Apr13.

MARK JOB

From: (b)(6) (b)(4) Third Party
Sent: Friday, April 19, 2013 2:17 PM
To: (b)(4) Third Party
Cc: (b)(6)
Subject: Review of Responses dated April 3, 2013
Attachments: Broncus Medical LungPoint Tools Deficiencies 19 Apr 2013.doc

Dear (b)(6)

We have completed our review of the Responses dated April 3, 2013 to (b)(4) Third Party Information.

(b)(4). These deficiencies are described in the attached Record of Deficiencies from the Substantive Review. Your submission has been placed on hold until we receive your response to the deficiencies.

If you have any questions, please do not hesitate to contact me. You may reach me at (b)(4) or this email address: (b)(4)

Sincerely,
(b)(6)
Reviewer
(b)(4)

Record of Deficiencies From Substantive Review

Device Name or Model Name: LungPoint® Tools (LungPoint Sheath, LungPoint Dilation Balloon)

Date: April 19, 2013

Please provide the following items as required according to the 510(k) checklist, the FDA Guidance for Industry and FDA Staff on Format for Traditional and Abbreviated 510(k)s issued August 12, 2005, and the Draft Guidance on Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile issued December 12, 2008.

We request that you provide detailed item-by-item responses to this request for additional information. The suggested format is to restate the question and/or comment, state your response to the request/recommendation, and reference the location of the appropriate supporting documentation in the response documents.

(b)(4) Deficiencies

[redacted]

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

Record of Deficiencies from Substantive Review

(b)(4) Deficiencies

[redacted]

This page represents the additional information provided by the sponsor.

Please see the enclosed Sponsor eCopy in

Folder labeled as

VOL_003_Response to 20Mar13.

MARK JOB

From: (b)(6) (b)(4)
Sent: Wednesday, March 20, 2013 12:08 PM
To: (b)(4)
Cc: (b)(6)
Subject: Questions on Broncus Medical LungPoint Tools
Attachments: Broncus Medical LungPoint Tools Deficiencies 20 Mar 2013.doc

Dear (b)(6)

We have completed both the administrative and the substantive review according to the 510(k) checklist, the FDA Guidance for Industry and FDA Staff on Format for Traditional and Abbreviated 510(k)s issued August 12, 2005, and the Draft Guidance on Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile issued December 12, 2008.

(b)(4). These deficiencies are described in the attached Record of Deficiencies from the Substantive Review. Your submission has been placed on hold until we receive your response to the deficiencies.

If you have any questions, please do not hesitate to contact me. You may reach me at (b)(4) or this email address: (b)(4)

Sincerely,
(b)(6)
Reviewer
(b)(4)

Record of Deficiencies From Substantive Review

Device Name or Model Name: LungPoint® Tools (LungPoint Sheath, LungPoint Dilation Balloon)

Date: March 20, 2013

Please provide the following items as required according to the 510(k) checklist, the FDA Guidance for Industry and FDA Staff on Format for Traditional and Abbreviated 510(k)s issued August 12, 2005, and the Draft Guidance on Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile issued December 12, 2008.

We request that you provide detailed item-by-item responses to this request for additional information. The suggested format is to restate the question and/or comment, state your response to the request/recommendation, and reference the location of the appropriate supporting documentation in the response documents.

(b)(4)

(b)(4)

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Date: March 4, 2013

(b)(6)
Broncus Technologies, Inc.
1400 N Shoreline Blvd, Suite A8
Mountain View, CA 94043

Re: LungPoint Tools

Dear (b)(6)

This letter is to acknowledge on March 4, 2013, (b)(4) (b)(4) received the 510(k) dated March 1, 2013 for the LungPoint Tools.

We will keep you informed as the review progresses.

If you have any questions, please do not hesitate to contact me. You may reach me (b)(4) or email at (b)(4)

Sincerely,

(b)(6)

Part Acceptance / Non-acceptance

1. Accredited Person:

Name: (b)(4) Third Party Information

Address

Contact: (b)(6)

Telephone: (b)(4) Third Party Information Fax: (b)(4) Third Party Information

2. Foreign Accredited Person, Specify a Domestic Correspondent:

Name: N/A

Address

Contact:

Telephone: Fax:

3. 510(k) Owner (Applicant, Manufacturer, other persons preparing 510(k))

Name: Broncus Medical, Inc.

Address 1400 N. Shoreline Boulevard, Suite A8

Mountain View, CA 94043

Contact: (b)(6), Regulatory Affairs Consultant

Telephone: 650-428-1600 Fax: 650-428-1542 (b)(4)

STOP!

Before completing items 4 to 9 below, complete pages 3 – 6 of this document.

4. Device Name:

Trade or Proprietary Name: LungPoint® Tools (LungPoint Sheath, LungPoint Dilation Balloon)

Classification Name: Bronchoscope and Accessories; product code EOQ

5. CFR Classification Citation: 21 CFR 874.4680 (see 21 CFR 862 through 892)

6. Classification Panel: Ear, Nose, and Throat

7. Based on my completion of this document, I recommend that this 510(k):

☒ Be accepted for substantive review and I have notified the 510(k) owner using RPP-F-0016.

☐ Not be accepted for substantive review and I have listed the deficiencies on RPP-F-0016.

8. Primary Reviewer

(b)(6)

3/15/13
Date

Print Name

9. Supervisor

(b)(6)

4/29/13
Date

Print Name

Checklist Questions:	YES	NO	Instructions
1. a). Is the device one that FDA has determined as being acceptable for third party review?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
1 b). Have you confirmed that the manufacturer has not engaged in forum shopping?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
2. Is the device trade or proprietary name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
3. Is the device common or usual name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
4. Is the device classification name, class of the device, and regulation number (21 CFR 874.4680; product code EOQ) included?	☒	☐	If NO, note deficiency on RPP-F-0013.
5. Is the classification panel included?	☒	☐	If NO, note deficiency on RPP-F-0013.
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	☒	☐	If NO, note deficiency on RPP-F-0013.
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	☒	☐	If NO, note deficiency on RPP-F-0013.
8. Does the submission contain the "Indications for Use" form?	☒	☐	If YES, indicate page number 17. If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
9. Does the submission contain an acceptable 510(k) Summary of Safety and Effectiveness (per 21 CFR 807.92) OR an acceptable 510(k) Statement (per 21 CFR 807.93) that safety and effectiveness information will be made available to any person upon request?	☒	☐	If YES, indicate page number Appendix A . If NO, note deficiency on RPP-F-0013.
10. Does the submission contain photographs of the device if applicable?	☒	☐	If NO, note deficiency on RPP-F-0013.
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	☒	☐	If NO, note deficiency on RPP-F-0013.
12. Does the submission identify the device to which equivalence is claimed?	☒	☐	
13. If the answer to question 12 is YES, did the applicant identify:			
a. Predicate device (referred to as marketed device)?	☐	☒	
b. Legally marketed device (referred to as marketed device)?	☒	☐	Note deficiency on RPP-F-0013.
Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a pre-amendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA has determined is SE to another marketed device (21 CFR 807.92(a)3). IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE. If it is not, the review must STOP. Telephone DSMA for assistance.			List all 510(k) control numbers: K112051 (SE 10/12/2011) K110093 (SE 02/11/2011) K023337 (SE 11/18/2002)

Checklist Questions:	YES	NO	Instructions
14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?	☒	☐	If NO, note deficiency on RPP-F-0013.
15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)	☒	☐	If NO, note deficiency on RPP-F-0013.
16. Does the submission contain the Truthful and Accurate Statement (per 21 CFR 807.87(j))?	☒	☐	If YES, indicate page number 19. If NO, note deficiency on RPP-F-0013.
17. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
18. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
19. Does the submission contain a table of contents with pagination?	☒	☐	If NO, note deficiency on RPP-F-0013.
20. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?	☒	☐	If NO, note deficiency on RPP-F-0013.
21. Does the submission contain a comparison table of the new device to the marketed device?	☒	☐	If NO, note deficiency on RPP-F-0013.
22. Does the submission contain information about the action taken to comply with voluntary standards?	☒	☐	If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
23. Does the submission contain performance data (can be bench or animal but not clinical), i.e.: Is there performance data for the marketed device? a. Bench testing? b. Animal testing? Is there performance data for the new device? a. Bench testing? b. Animal testing?	 ☐ ☐ ☒ ☐	 ☒ ☒ ☐ ☒	 If NO, note deficiency on RPP-F-0013. Predicate device bench and animal testing is not required. If NO, note deficiency on RPP-F-0013. New device animal testing is not required.
24. If the device is labeled as sterile, does the submission contain sterilization data?	☒	☐	If NO, note deficiency on RPP-F-0013.
25. Does the device incorporate a computer or computer software? a. If YES, is there information about the hardware? b. If YES, is there information about the software?	☐ ☐ ☐	☒ ☐ ☐	If NO, note deficiency on RPP-F-0013. No software
26. a) Is there a specific guidance document for this type of device? Title: _____	☐	☒	If YES, continue review with checklist from the specific guidance document and return to question 27. If NO, proceed to question 26 b).
26 b) Contact the appropriate ODE Branch Chief to obtain information for reviewing this type of device. Has a summary of this discussion been documented?	☒	☐	If YES, answer question 27. If NO, do not proceed to question 27; stop review until summary completed.
27 Is this 510(k) sufficiently complete to allow substantive review?	☒	☐	If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms. If NO, note deficiency on RPP-F-0013.

Broncus Medical, Inc.
1400 N. Shoreline Blvd.
Suite A8
Mountain View, CA 94043
www.broncus.com

(650) 428-1600
(650) 428-1542 fax

March 1, 2013

(b)(4)
Attention (b)(6)
(b)(4)

Re: Authorization for Accredited Person Review of 510(k)

Dear (b)(6)

Enclosed is the Traditional 510(k) for Broncus' LungPoint Tools.

We at Broncus Medical, Inc hereby authorize (b)(4) to submit the enclosed 510(k) to the Food and Drug Administration (FDA) on our behalf, discuss its contents with the FDA, and function as the Accredited Person to perform the third party review.

We certify that we have not established a contract with another Accredited Person to perform the review of this 510(k) submission.

We accept the quote for the Traditional 510(k) review services, including the (b)(4) (b)(4) Terms and Conditions.

Additionally, a completed Refuse to Accept Checklist is attached for your reference. Should you have any questions, please contact me at (b)(4) (b)(4) or by e-mail at (b)(4)

Sincerely,

(b)(6)

Consulting Regulatory Affairs Director

Enclosure

TRADITIONAL 510(k)

LungPoint® Tools

Broncus Medical, Inc.
1400 N. Shoreline Boulevard
Suite A8
Mountain View, CA 94043

Table of Contents

List of in-text figures

List of in-text tables

Appendices

ABBREVIATIONS & TERMINOLOGY

Abbreviation or Terminology	Definition
FMECA	Failure modes and effects criticality analysis
HID	Hazard identification
QA	Quality assurance
R&D	Research and development
V&V	Verification and validation

(The remainder of this page is intentionally left blank.)

1. MDUFMA COVER SHEET

This section is not applicable since the submission is being submitted through (b)(4) (b)(4), a third party reviewer, who is listed on the FDA website (as of 2/28/2013) as an accredited person for premarket submission review.

(The remainder of this page is intentionally left blank.)

2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

FDA Form 3514 is included on the following page.

(The remainder of this page is intentionally left blank.)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03/01/2013	NA	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Broncus Medical, Inc	3007867778		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	650-428-1600		
Street Address	FAX Number *(including area code)*		
1400 N Shoreline Ave Suite A8	650-428-1542		
City	State / Province	ZIP/Postal Code	Country
Mountain View	CA	94043	USA
Contact Name			
(b)(6)			
Contact Title	Contact E-mail Address		
Regulatory Affairs Consultant	(b)(4)		

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		

PSC Publishing Services (301) 443-6740 EF

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

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

- ☐ 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

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

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

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	EOQ	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	K112051	1	LungPoint Software	1	Broncus Medical, Inc
2	K110093	2	inReach System	2	SuperDimension (Covidien)
3	K023337	3	CRE Pulmonary Balloon Dilatation Catheter	3	Boston Scientific Corporation
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Bronchoscope and Accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	LungPoint Tools (LungPoint Sheath and LungPoint Dilation Balloon)	1	
2		2	
3		3	
4		4	
5		5	

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

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
EOQ	21 CFR 874.4680	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Bronchoscope and Accessories		

Indications *(from labeling)*

The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

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

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

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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	11737-1	ANSI/AAMI/ISO	Sterilization of health care products - Microbiological methods - Part 1	2nd edition	04/01/2006
2	11737-2	ANSI/AAMI/ISO	Sterilization of health care products - Microbiological methods - Part 2	2nd edition	11/15/2009
3	11137-2	ANSI/AAMI/ISO	Sterilization of health care products - Radiation - Part 2	2nd edition	03/15/2012
4	11607-01	ISO	Packaging for terminally sterilized medical devices - Part 1	2006	01/01/2006
5	see attached for additional standards		see attached for additional standards		
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.

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

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

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

STANDARDS TO BE CITED:					
Item No.	**Standard Number**	**Standards Organization**	**Standards Title**	**Version**	**Date**
6	10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a Risk Management Process	4th edition	10/15/2009
7	10993-5	ISO	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	3rd edition	06/01/2009
8	10993-10	ISO	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	3rd edition	08/01/2010
9	10993-11	ISO	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	2nd edition	08/15/2006
11	10555-1	IEN/ISO	Sterile, Single-use Intravascular Catheters – Part 1: General Requirements	1st edition A2	05/15/2004
12	1618	BS EN	Catheters other than intravascular catheters. Test methods for common properties	2001	2001

3. 510(K) COVER LETTER

The cover letter is included on the following page.

(The remainder of this page is intentionally left blank.)

Broncus Medical, Inc.
Suite A8
Mountain View, CA 94043
www.broncus.com

March 1, 2013

(b)(4)
Attention: (b)(6)
(b)(4)

Re: Traditional 510(k) Notification - Broncus' LungPoint Tools

Dear (b)(6)

In accordance with 21 CFR 807 and FDA guidance entitled *Format for Traditional and Abbreviated 510(k)s* (August 2005), Broncus Medical, Inc, is submitting this Traditional 510(k) for the LungPoint Tools. The LungPoint Tools are Class II endoscopic tools used during bronchoscopic procedures.

The Traditional 510(k) is being submitted by Broncus to address the addition of two endoscopic accessories, referred to collectively as the LungPoint Tools. A previous submission was made to (b) for the LungPoint Tools as Special 510(k) to the LungPoint Software. Per our discussions, we are now submitting the LungPoint Tools as a separate Traditional 510(k).

The format of the submission is consistent with that required in the FDA guidance entitled *Format for Traditional and Abbreviated 510(k)s* (August 2005).

In accordance with 21 CFR 807.95, Broncus requests that ((b) nd FDA hold the contents of this submission as confidential. Broncus has taken precautions to protect the confidentiality of this information, and understands that the submission to the government of false information is prohibited by 18 USC 1001 and 221 USC 331(q).

Should you have any questions, please contact me at (b)(4) 3 or by e-mail at (b)(4)

Sincerely,

(b)(6)

Consulting Regulatory Affairs Director

4. INDICATIONS FOR USE STATEMENT

The indication for use statement is included on the following page.

The intended use and indications of the LungPoint Tools, as described in its labeling, are the same as the intended use and indications for the predicate devices. **Section 12** provides a detailed comparison table.

Indications for Use

510(k) Number (if known): K_____

Device Name: LungPoint Tools - LungPoint Dilation Balloon and LungPoint Sheath

Indications for Use: The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

_____
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____ Page __ of ___

5. 510(K) SUMMARY

A 510(k) Summary of Safety and Effectiveness appears as **Appendix A** and is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990. This 510(k) Summary meets the requirements identified in 21 CFR 807.92.

(The remainder of this page is intentionally left blank.)

7. CLASS III SUMMARY AND CERTIFICATION

This section is not applicable since this 510(k) is for a Class II device and not for a device type classified into Class III.

(The remainder of this page is intentionally left blank.)

8. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section is not applicable since data from clinical studies is not used to support this submission.

(The remainder of this page is intentionally left blank.)

6. TRUTHFUL AND ACCURACY STATEMENT

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Operating Office of Broncus Medical, Inc., 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.

Gary Kaplan
Chief Operating Office

3/1/13
Date

K_____
510(k) Number

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

The development activities of the LungPoint Tools conformed to the following FDA-recognized standard. FDA Forms 3654 for each standard listed are included in **Appendix I**.

Table 9-1. List of Relevant Standards

Standard Number	Standards Title	Version
Sterilization, Packaging and Shelf-life		
ANSI/AAMI/ISO 11737-1	Sterilization of health care products – Microbiological methods – Part 1: Determination of the population of microorganisms on product	2006
ANSI/AAMI/ISO 11737-2	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process	2009
ISO 11137-2	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose	2012
ISO 11607-1	Packaging for terminally sterilized medical devices – Part1: Requirements for materials, sterile barrier systems and packaging systems	2006
Biocompatibility		
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a Risk Management Process	2009
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	2009
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	2010
ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	2009
Bench Testing		
IEN SO 10555-1	Sterile, Single-use Intravascular Catheters – Part 1: General Requirements	1995
BS EN 1618	Catheters other than intravascular catheters - Test methods for common properties.	1997

11. DEVICE DESCRIPTION

The LungPoint Sheath and LungPoint Dilation Balloon are endoscopic tools, which are intended to be used as accessories to the LungPoint Software. They are described in more detail in Sections 11.1 and 11.2, respectively. The LungPoint Software may be used with these tools or other commercially available tools. However, these tools have been specifically designed to be used with the Software but can be used without the LungPoint Software, as well.

11.1. LungPoint Sheath

The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs.

(b)(4) [redacted]

The sheath (b)(4) [redacted]) is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools, such as the dilation balloon described in the next section. Once placed, other endoscopic tools, such as needles, dilation balloons, or other endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. (b)(4) [redacted] (b)(4) [redacted] other tools.

The LungPoint Sheath is provided as a sterile device for single use and is available in one size. A detailed drawing of the sheath is provided in **Appendix B.**

11.1.1. Materials

The materials used in the sheath are outlined below. All materials passed appropriate biocompatibility requirements as outlined in **Section 16**.

Table 11.1.1-1: LungPoint Sheath Materials List

Material Use	Material Description	Common Name
(b)(4) [redacted]		

Material Use	Material Description	Common Name
(b)(4)		

Supporting Information
Material Safety Data Sheet (MSDS)
Certificate of Analysis

(b)(4) [redacted]

chemicals and their relative concentrations are included in the Material Safety Data Sheet (MSDS), as summarized in the table below.

(b)(4) [redacted]

Supporting information on the (b)(4) [redacted] is included in **Appendix C2** as outlined below.

Supporting Information
Material Safety Data Sheet (MSDS)
(b)(4) [redacted]

11.1.2. Performance Specification

Performance specification of the device, acceptance criteria and rationale for the acceptance criteria for each specification to ensure safe and effective use are outlined below.

Table 11.1.2-1: LungPoint Sheath Performance Specifications (D0210-007 B)

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
Dimensional Testing	(b)(4) [redacted]	NA – all criteria are per the product specifications	(b)(4) [redacted]

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
	(b)(4)		(b)(4)
Joints/ Tensile Test		Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995	
Simulated Use		NA – validated test fixture	

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
Radiopacity	(b)(4)	NA	(b)(4)

11.2. LungPoint Dilation Balloon

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung (b)(4)
(b)(4)

The LungPoint Dilation Balloon is provided as a sterile device for single use. When inflated (b)(4)
.

The materials used in the dilation balloon are outlined below.

Table 11.2-1: LungPoint Dilation Balloon Materials List

Material Use	Material Description	Trade Name
(b)(4)		

Performance specification of the device and acceptance criteria for each specification to ensure safe and effective use are outlined below.

Table 11.2-2: LungPoint Balloon Performance Specifications (D0210-007_B)

Test Title	Objective	Applicable Standards	Acceptance Criteria
Dimensional Testing	(b)(4)	NA – all criteria are per the product specifications	(b)(4)
Joints/ Tensile Test		Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995	
Simulated Use		NA – validated test fixture	
Balloon burst pressure		NA	

Test Title	Objective	Applicable Standards	Acceptance Criteria
Radiopacity	(b)(4) [redacted]	NA	(b)(4) [redacted]

10. EXECUTIVE SUMMARY

10.1. Background and Rationale

This Traditional 510(k) is being submitted by Broncus Medical, Inc to add two endoscopic tools – a sheath ([redacted] and a dilation balloon - to the LungPoint Software System (version 3.0 of the software was previously cleared in combination with an aspiration needle called FlexNeedle under K112051).

[redacted]

10.2. Description of Device

The LungPoint Sheath and LungPoint Dilation Balloon are endoscopic tools used during [redacted]. Additionally, both devices are standard bronchoscopic tools, which can be used without the LungPoint Software.

10.3. Device Comparison

The LungPoint Tools - LungPoint Sheath and Dilation Balloon - has the same intended use and technological characteristics as the predicate devices. Table 1 in Section 12 provides a detailed comparison of the LungPoint Sheath and Dilation Balloon and the predicate devices. Based on the information provided, Broncus believes that the LungPoint Tools do not introduce any new questions of safety and effectiveness and are substantially equivalent to the predicate devices.

10.4. Summary of Performance Testing

The design and safety of the LungPoint Sheath and LungPoint Dilation Balloon were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use. Section 18 provides an overview of the performance testing conducted to support this premarket submission.

12. SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1. Predicate Devices

The LungPoint Tools, which are designed to be used as accessories to the LungPoint Software System (with FlexNeedle) - cleared to market on October 12, 2011 (K112051), are commonly used endosopic tools. These tools can be used as stand-alone devices or with the use of software like the LungPoint Software or its predicate the inReach System.

(b)(4)

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System (with FlexNeedle)	Broncus Technologies, Inc*	K112051, cleared to market on October 12, 2011 (and K093423, K091160 and K090095, by reference)
inReach System	SuperDimension	K110093, cleared to market on February 11, 2011 (and K071473, K092365 and K102604, by reference)
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002
*NOTE: Broncus Technologies, Inc changed their name to Broncus Medical, Inc in June 2012.		

12.2. Comparison to the Predicate Devices

The following tables outline the similarities and differences between the LungPoint Tools and the predicate devices.

Table 12.2-1: Comparison Table - LungPoint Sheath

	I-Logic inReach System (K110093)	LungPoint Sheath
Intended Use	No separate intended use exists for the guide sheath/catheter – it is sold as part of the inReach system and is used with the software and bronchoscopes to provide a pathway through which endoscopic tools, such as needles, dilation balloons, or other diagnostic/therapeutic devices may be introduced to the targeted area within the respiratory organs.	No separate intended use exists for the sheath – it is sold as part of the LungPoint Software System and is used to provide a pathway through which endoscopic tools, such as needles, dilation balloons, or other diagnostic/therapeutic devices may be introduced to the targeted area within the respiratory organs.
(b)(4)		
Radiopaque Markers on Sheath/Stylet	Yes	Yes
(b)(4)		
Delivered Through	Flexible bronchoscope with minimum working channel of (b) mm	Flexible bronchoscope with minimum working channel of (b) .mm
Single Use	Yes	Yes
Sterilization Method	(b)(4)	

Table 12.2-2: Comparison Table - LungPoint Dilation Balloon

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	LungPoint Dilation Balloon
Intended Use	Used to endoscopically dilate strictures of the airway tree.	No separate intended use exists for the dilation balloon – as with the inReach System, it is sold as part of the Software System. The Dilation Balloon is used to endoscopically dilate the target tissue of the airway tree.
Balloon Size and Inflation (rated balloon pressure)*	(b)(4) [redacted]	
Catheter Length		
Inflation Port		
Balloon Length*		
Balloon Inflation Method		
Delivery		
Single Use		
Sterilization Method		

(b)(4) [redacted]

12.3. Substantial Equivalence Discussion

The LungPoint Sheath and Dilation Balloon, the subject devices of this premarket notification, are substantially equivalent to the predicate devices. As outlined above, the LungPoint Tools have the same intended use and technological characteristics as the predicate devices.

In making this determination, Broncus followed the FDA's Draft Guidance entitled The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (December 27, 2011), the detailed flowchart provided in the guidance (included at the end of this section) and 21 CFR 807.100.

Specifically the following questions were considered:

Decision 1: *Is the predicate device legally marketed?*
Yes all predicates are legally marketed. Specifically,

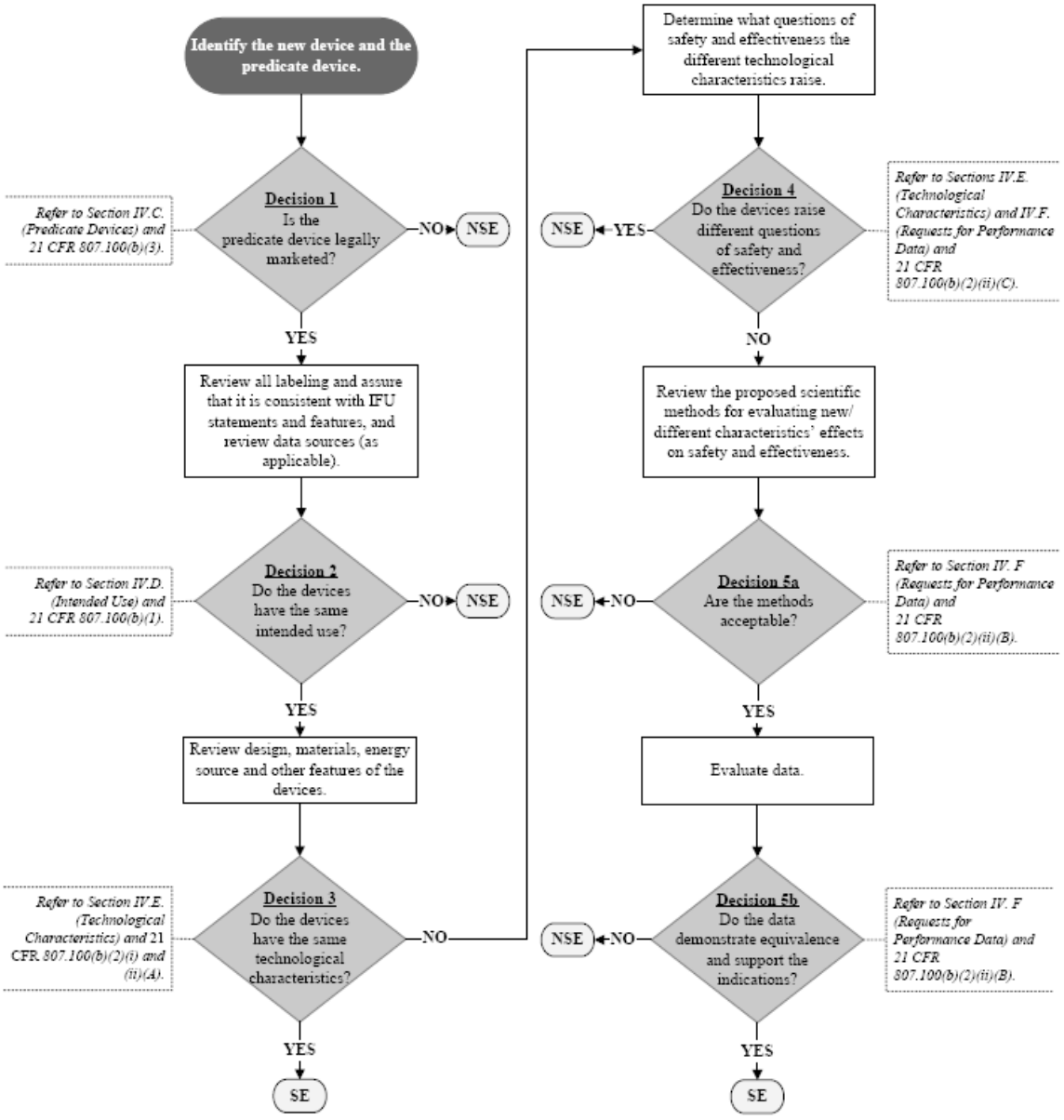
- the LungPoint Software System with FlexNeedle received clearance on October 12, 2011 (K112051),
- the inReach System received 510(k) clearance on February 11, 2011 (K110093), and
- the CRE Pulmonary Balloon received clearance on November 18, 2002 (K023337).

Decision 2: *Do the devices have the same intended use?*
The LungPoint Tools are accessories to the LungPoint Software System similar to (b)(4) [redacted] (b)(4).

Decision 3: *Do the devices have the same technological characteristics?*
Yes, the individual endoscopic tools provided with the software have the same technological characteristics as those currently on the market (refer to Table 12.2-1 and Table 12.2-2). Data supporting their performance, biocompatibility and sterility is included in the appropriate sections of this 510(k) submission.

The difference (b)(4) [redacted]

Conclusions: Based on the analysis above, Broncus believes that the LungPoint Tools do not introduce any new questions of safety and effectiveness and are substantially equivalent to the predicate devices.



SE = "Substantially Equivalent"
NSE = "Not Substantially Equivalent"

This Flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.

Figure 1: 510(k) "Substantial Equivalence" Decision-Making Flowchart

13. PROPOSED LABELING

The labeling for the LungPoint Tools is provided in **Appendix D**. It includes the following:

- LungPoint Software and Tools Instructions for Use Addendum
- LungPoint Sheath Instructions for Use
- LungPoint Dilation Balloon Instructions for Use

All labeling was created in accordance with 21 CFR 801.

The 510(k) summaries for the predicate devices are included in **Appendix E**.

(The remainder of this page is intentionally left blank.)

15. BIOCOMPATIBILITY

Biocompatibility data is being submitted for the accessories being added to the LungPoint Software, specifically the LungPoint Sheath and LungPoint Dilation Balloon.

15.1. Overview

Biocompatibility testing was performed for both the LungPoint Sheath components (b)(4) [redacted]

15.2. Materials in Contact with Patients

Table 15.2-1 and Table 15.2-2 provide an overview of the components of the LungPoint Sheath and LungPoint Dilation Balloon, respectively. The list identifies whether the devices (b)(4) [redacted].

Table 15.2-1: LungPoint Sheath Materials List

Material Description	Material	Patient Contact (Yes/No)
(b)(4) [redacted]		

Table 15.2-2: LungPoint Dilation Balloon Materials List

Material Description	Material	Patient Contact (Yes/No)
(b)(4)		

15.3. Biocompatibility Summary

The devices were evaluated for biocompatibility per ISO 10993-1:2009 requirements for Biological Evaluation of Medical Devices. Testing was performed (b) (b)(4) on post-sterilized devices per the contract testing facility's GLP protocols to meet the testing requirements summarized in Table 15.3-1.

Based on ISO 10993-1, the following tests were conducted.

Table 15.3-1: Testing Requirements ISO 10993-1

Test Article	ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and Testing	Biological Effect
(b)(4)		

Table 15.3-2 summarizes the biocompatibility test results for the devices. Biocompatibility results show that both devices meet all test requirements. The complete test report is provided in **Appendix G.**

Table 15.3-2: Testing Summary for LungPoint Tools

Test Name	Test Description	Results
(b)(4)		
Test Report Reference: (b)(4)		

Based on the results of the biological testing, it can be concluded that the tissue contact with the devices does not result in adverse biological effects. Therefore, the LungPoint Tools are considered biocompatible, non-toxic, and safe for use as external communicating devices in limited contact with tissue.

14. STERILIZATION/SHELF LIFE

Sterilization data is being submitted for the LungPoint Sheath and LungPoint Dilation Balloon.

14.1. Overview

The LungPoint Sheath and LungPoint Dilation Balloon are both provided sterile for single (b)(4)

Both products are (b)(4)) sterilized at (b)(4) , a contract (b)(4) (b)(4)

Upon receiving the devices back from the sterilization facility, the cartons containing the sterilized devices are removed from the corrugated box, and it is verified that incoming quantities match the number of originally sent devices. The certificate of irradiation is reviewed for appropriate dose delivery. The verification of sterilization acceptance is required before the devices are placed into Finished Goods.

The standards that apply to the LungPoint Tools sterilization processes include:

Process	Standard	Standard Title
(b)(4)		

Process	Standard	Standard Title
(b)(4)		

The following sections describe the sterilization methods and validation for the Broncus devices.

14.2. Sterilization Process

Both devices are (b)(4) (b)(4) (b)(4)

(b)(4)

14.6. Pyrogenicity

The LungPoint Tools (b)(4).

14.7. Shelf-Life

Broncus plans to introduce both the LungPoint Sheath and LungPoint Dilation Balloon with (b)(4)

Testing of the LungPoint Tools includes the following performance specifications:

- Simulated Use Testing ((b)(4)
- Tensile (b)(4) testing)
- Balloon Fatigue and Burst Testing ((b)(4)

16. SOFTWARE

This section is not applicable as software is not included in this submission and the cleared LungPoint Software is not being modified to allow for the use of the LungPoint

(b)(4)

[redacted]

(The remainder of this page is intentionally left blank.)

17. ELECTROMAGNETIC COMPATIBILITY/ELECTRICAL SAFETY

This section is not applicable for the device as there are no electrical components.

(The remainder of this page is intentionally left blank.)

19. PERFORMANCE TESTING – ANIMAL

Biocompatibility studies for the LungPoint Sheath and LungPoint Dilation Balloon were performed as outlined in Section 15. No additional animal studies were performed in support of this premarket submission given that no changes were made to the software as a result of the addition of the LungPoint Tools to the LungPoint Software.

(The remainder of this page is intentionally left blank.)

18. PERFORMANCE TESTING – BENCH

18.1. Overview

(b)(4)

Requirements NOTE: Significance of each requirement has been modified form the FDA Guidance to remove references to stents	Applicable? Y/N	Rationale/Testing Conducted

(b)(4)

Requirements NOTE: Significance of each requirement has been modified form the FDA Guidance to remove references to stents	**Applicable? Y/N**	**Rationale/Testing Conducted**
(b)(4) Testing	[redacted]	[redacted]

Requirements NOTE: Significance of each requirement has been modified form the FDA Guidance to remove references to stents	**Applicable? Y/N**	**Rationale/Testing Conducted**
(b)(4) Testing		

In addition to the testing outlined above, radiopacity of the markers on the LungPoint Tools was also confirmed using images of the catheter. Images of the markers were obtained during software developments testing and are included in **Appendix H5.**

Detailed test results of the LungPoint Dilation Balloon and LungPoint Sheath are outlined in the following sections. Appropriate standards, where applicable, were used to set acceptance criteria as outlined in **Section 11**.

18.2. LungPoint Dilation Balloon

The design and safety of the LungPoint Dilation Balloon was verified by performing functional and performance testing. Testing included:

1. Dimensional testing – (b)(4) Testing
2. Tensile (b)(4) testing – (b)(4) Testing
3. Burst pressure and fatigue – (b)(4) Testing

Table 18.2-1: Summary of Bench Testing for the Broncus Balloon Dilation Catheter

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

18.3. LungPoint Sheath

The design and safety of the LungPoint Sheath was verified by performing functional and performance testing. Testing included:

1. Dimensional testing - (b)(4) Testing [redacted]
2. Tensile (b)(4) testing - (b)(4) Testing [redacted]

(b)(4) [redacted]

(b)(4) Testing

[redacted]

Table 18.3-1: Summary of Bench Testing for the LungPoint Sheath

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

20. PERFORMANCE TESTING - CLINICAL

When compared to the predicate device, the LungPoint Software with the LungPoint Sheath and LungPoint Dilation Balloon does not incorporate any changes that impact safety or efficacy; therefore, as with the predicate device, a clinical study was not performed to support the premarket submission.

(The remainder of this page is intentionally left blank.)

Appendix A: 510(k) Summary

510(k) Summary

1. Date of Summary

March 1, 2013

2. 510(k) Applicant

Broncus Medical, Inc.
1400 N. Shoreline Blvd, Suite A8
Mountain View, California 94043
Phone: (650) 428-1600
FAX: (650) 428-1542

Contact Person: Gary Kaplan
Phone: (650) 428-1600
Fax: (650) 428-1542
e-mail: gkaplan@broncus.com

3. Device Overview

Trade Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)

Common Name: Sheath and Dilation Balloon

Classification Name: Bronchoscope and Accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System (with FlexNeedle)	Broncus Technologies, Inc*	K112051, cleared to market on October 12, 2011 (and K093423, K091160 and K090095, by reference)
inReach System	SuperDimension	K110093, cleared to market on February 11, 2011 (and K071473, K092365 and K102604, by reference)
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002
*NOTE: Broncus Technologies, Inc changed their name to Broncus Medical, Inc in June 2012.		

5. Device Description

The LungPoint Tools are endoscopic tools used during bronchoscopy procedures. The LungPoint Sheath is designed to be used with a bronchoscope to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted lung tissue within the respiratory organs. It is advanced to a predefined target following guidance of the LungPoint Software. The LungPoint Dilation Balloon is used to dilate tissue of the bronchial tree and may be inserted through the sheath or directly through the working channel of the bronchoscope. Additionally, both devices could be used without the LungPoint Software.

6. Intended Use

The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs.

7. Comparison to Predicate Device

The LungPoint Tools have the same intended use and technological characteristics as the predicate devices.

8. Performance Data

The design and safety of the LungPoint Tools were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use.

9. Safety and Effectiveness

The LungPoint Tools labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the devices. The biocompatibility assessment of all patient contacting materials was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices*. In addition, the devices are sterilized using e-beam sterilization.

Appendix B: Device Drawings

Device drawing for the LungPoint Sheath (PN 12138) and LungPoint Balloon (PN 12139) are included.

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

Appendix C1: Supporting Information for (b)(4)

The following are included

1. MSDS (blue and green)
2. Certificate of Analysis (blue and green).

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

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(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

Appendix C2: Supporting Information for (b)(4) [redacted]

The following are included

1. MSDS
2. Technical Data Sheet
3. Class VI Certification
4. Class Testing for Plastics

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

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(b)(4) Manufacturing Information

Appendix D: Labeling

1. LungPoint Software and LungPoint Tools Instructions for Use Addendum (DRAFT)
2. LungPoint Sheath Instructions for Use (DRAFT)
3. LungPoint Dilation Balloon Instructions for Use (DRAFT)

LungPoint Software with Endoscopic Tools
Instructions for Use Addendum
DRAFT

LungPoint Overview

The LungPoint Software is a device that guides a bronchoscope and endoscopic tools to a prespecified target in or adjacent to the bronchial tree by providing a path which is displayed on a 3D reconstruction of CT scan. The Software allows for visualization of the target in the lung tissue or in the bronchial tree; visualization of the interior of the bronchial tree; placement of catheters in the bronchial tree; and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery. The LungPoint Software is intended to be used with various commercially available endoscopic tools.

Consult the LungPoint Software User Manual for detailed information about LungPoint.

LungPoint Tools

Broncus Medical provides the following endoscopic tools (referred to as LungPoint Tools) for use during Virtual Bronchoscopic Navigation. A brief description of each tool follows the table. The LungPoint Tools are ebeam sterilized, supplied sterile, for single patient use.

LungPoint Tool	Part Number	Description
FlexNeedle	10005	18 gauge
LungPoint Dilation Balloon*	TBD	Diameter x length: 4 x 6 mm Catheter length: 155 cm
LungPoint Sheath*	TBD	ID/OD: 2.0/2.6 cm Catheter length: 100 cm

*NOTE: The LungPoint Sheath and Balloon are for use with the LungPoint Software only.

Caution: *U.S. Federal law restricts the sale, distribution, and use of these devices to, or on the order of, a physician.*

FlexNeedle
The FlexNeedle is an aspiration needle commonly used to collect specimens for histophatology or cytopathology. The needle has a coring needle tip in a protective sheath that is designed to fit down the 2-mm working channel of a standard flexible optical bronchoscope. The needle tip is welded to a coil tube that comprises a flexible shaft, allowing the needle to bend with the bronchoscope articulation and enabling access to hard-to-reach locations. When used together with the LungPoint Software, the needle can be safely guided to a prespecified targeted area within the respiratory organs in order to collect specimens.

LungPoint Dilation Balloon
The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or sheath and is used to dilate lung tissue. The balloon may be used during interventional bronchoscopy procedures as determined by the physician performing the bronchoscopy.

LungPoint Sheath
The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs.

The sheath (with stylet, if necessary) is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools, such as the dilation balloon described in the next section. Once placed, other endoscopic tools, such as needles, dilation balloons, or other endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. If a stylet is used, it must be removed prior to the introduction of the other tools.

WARNINGS AND CAUTIONS: LungPoint Tools

- The LungPoint Tools are supplied sterile and for single use only. Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.
- If any damage or irregularity is found to the device after opening, DO NOT USE the device as this could result in harm to the patient.
- DO NOT USE the device past its "Use Before" (expiration) date.
- DO NOT USE the LungPoint Sheath with active devices.

Caution: *U.S. Federal law restricts the sale, distribution, and use of these devices to, or on the order of, a physician.*

Broncus Medical Inc.

LungPoint™ Sheath

REF **Catalog number 10007**

Instructions For Use (IFU)

Table of Contents

PN xxxxx_01 DRAFT

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs.

The sheath enables physicians to easily access targets and allows for multiple approaches to the preselected target. It allows for the repeated placement of endoscopic tools to a specified lesion(s) during one procedure. The sheath is provided with a stylet, which is used to minimize the amount of airway mucosa entering the sheath's lumen and/or to provide rigidity (i.e. pushability).

The sheath (with stylet, if necessary) is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools. Once placed, other endoscopic tools, such as needles, dilation balloons, or other endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. If a stylet is used, it must be removed prior to the introduction of the other tools.

The LungPoint Sheath is comprised of a braid reinforced tubing,to resist kinking with articulation along with an incorporated stylet. The stylet when mated, provides for a rounded tip during insertion and pushability for navigation to the target. Removal of the stylet allows for standard 2.0mm working channel bronchoscopic accessories to be used though the lumen of the sheath. The tip of the Sheath is marked visually with black bands at the tip and in 1cm increments to 6cm to provide the user with an indication of the traveled depth during insertion. Also included are multiple radiopaque marker bands at the distal end @ the tip, 5mm, 10mm and 20mm to aid visualization of the sheath under fluoroscopy.

The LungPoint Sheath is designed to be used as a stand-alone device or with the LungPoint Software.

Product Configuration and Dimensions

The LungPoint Dilation Balloon (see illustration in Figure 1) has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

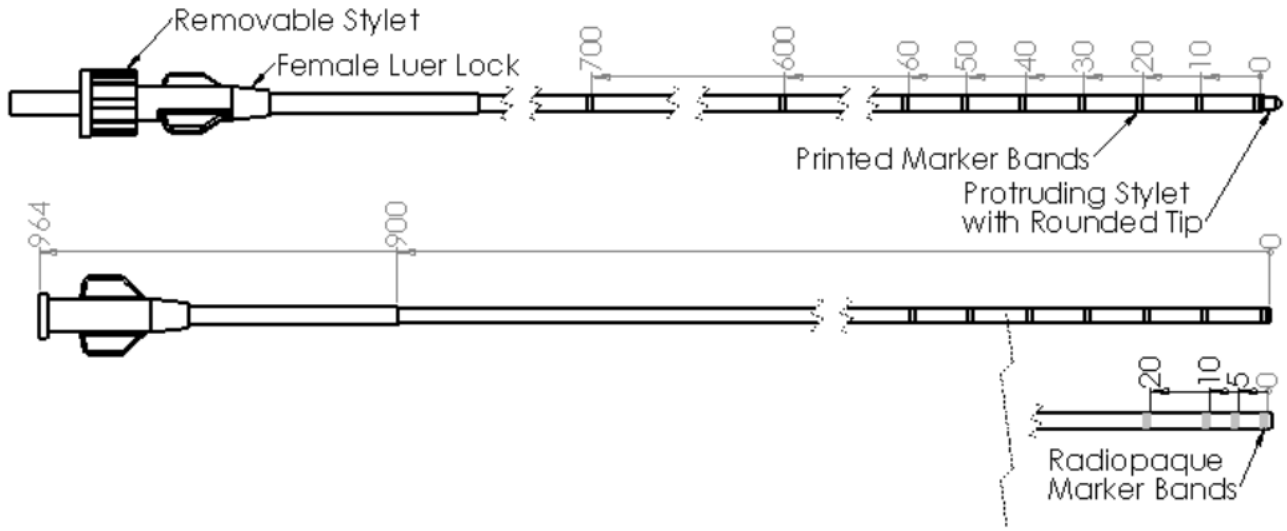

Figure 1: LungPoint Sheath

2 Intended Use

The LungPoint Sheath is intended to provide a pathway through which endoscopic tools, such as needles, dilation balloons, or other diagnostic/therapeutic devices may be introduced to the targeted area within the respiratory organs.

3 Contraindications

There are no known contraindications.

WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Sheath should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- DO NOT USE the LungPoint Sheath with active devices.
- While advancing the sheath, DO NOT USE excessive force as this may advance the device in an uncontrolled manner that could result in harm to the patient's airway wall and cause bleeding.
- The LungPoint Sheath should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Sheath in contradiction to the instructions may harm the device, bronchoscope or patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

6.1 Materials Required

- LungPoint Sheath
- Luer-lock aspiration syringe
- Flexible bronchoscope with a working channel of 2.8 mm or greater

6.2 Device Inspection and Preparation

6.2.1 Read all IFUs, package inserts, labels, and warnings for the device before beginning the procedure.

CAUTION: **Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.**

6.2.2 Aseptically remove the LungPoint Sheath from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: **If any damage or irregularity is found,** DO NOT USE **the device as this could result in harm to the patient.**

CAUTION: DO NOT USE **the device past its "Use Before" (expiration) date.**

6.2.3 Before inserting the device into the working channel of the bronchoscope, verify that the stylet is secured to the sheath via the luer lock connection.

7 Operating Instructions

7.1 Carefully advance the Sheath through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 For accessory use: remove the stylet by loosening the luer lock connection and withdraw the stylet. Insert the accessory device into the lumen.

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the sheath, accessory or bronchoscope.

7.4 If using fluoroscopy – visualize radiopaque accessory devices position relative to the tip marker band.

7.5 Withdraw the Sheath from the bronchoscope.

7.6 At the completion of the patient procedure, discard the device in the appropriate disposal container.

8 Storage

Store at controlled room temperature.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.
!	Caution: consult instructions for use
STERILE R	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
LOT	Serial number or batch code
	Use before
2	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Broncus Medical Inc.

LungPoint™ Dilation Balloon

REF **Catalog number 10008**

Instructions For Use (IFU)

Table of Contents

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or other endoscopic tool, such as a sheath, and is used to dilate lung tissue. The balloon may be used during interventional bronchoscopy procedures as determined by the physician performing the bronchoscopy.

The LungPoint Dilation Balloon is comprised of a catheter with a non-compliant 4mm OD x 6mm long inflatable balloon at the distal end and a y-connector with female luer fittings at the proximal end. The side port of the Y connector is used for inflation and deflation of the balloon with a standard indeflator capable of 12atm pressure (typically with a gage) and a male luer lock connector. The center port contains a nitinol wire which is fixed in place for pushability and kink resistance during tortuous bronchoscopic navigation. Included are two radiopaque marker bands and the distal and proximal ends of the balloon inflation length for visualization of the device position under fluoroscopy

The LungPoint Dilation Balloon is designed to be used as a stand-alone device or with the LungPoint Software.

Product Configuration and Dimensions

The LungPoint Dilation Balloon (see illustration in Figure 1) has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	12atm	1mm	1430mm/975mm

2 Intended Use

The LungPoint Dilation Balloon is intended to endoscopically dilate the target tissue of the airway tree.

3 Contraindications

There are no known contraindications.

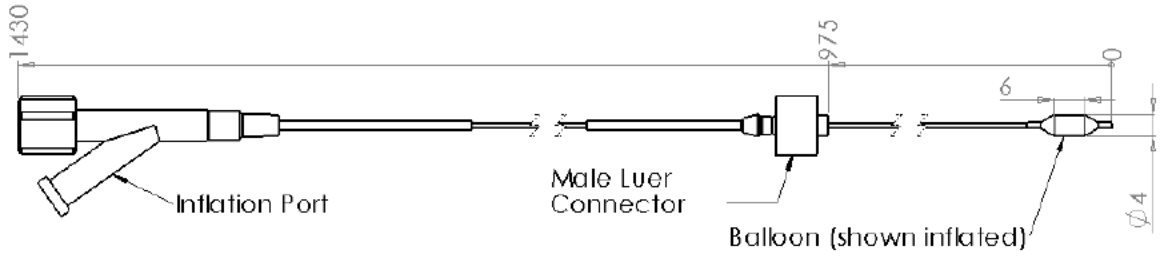

Figure 1: Dilation Balloon (shown inflated)

⚠ WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Dilation Balloon should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- The LungPoint Dilation Balloon should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Dilation Balloon in contradiction to the instructions may harm the device, bronchoscope or patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

5.1 Materials Required

- LungPoint Dilation Balloon
- Indeflator capable of 12atm
- Flexible bronchoscope with a working channel of 2.0 mm or greater

5.2 Device Inspection and Preparation

5.2.1 Read all IFUs, package inserts, labels, and warnings for the LungPoint Dilation Balloon before beginning the procedure.

CAUTION: Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.

5.2.2 Aseptically remove the LungPoint Dilation Balloon from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: If any damage or irregularity is found, **DO NOT USE** the device as this could result in harm to the patient.

CAUTION: DO NOT USE the device past its “Use Before” (expiration) date.

CAUTION: DO NOT place or manipulate the catheter in the airways unless under direct visualization with a bronchoscope as this may result in harm to the patient.

7 Operating Instructions

7.1 Carefully advance the balloon through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 Connect the indeflator via the luer lock connector and inflate to 10atm. Do not exceed the rated burst pressure of 12 atm.

7.4 If using fluoroscopy – visualize balloon inflation location via the radiopaque marker bands and the distal and proximal ends of the balloon inflation length.

7.5 Deflate the balloon, and remove the device

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the device or bronchoscope.

7.6 At the completion of the patient procedure, discard the device in the appropriate disposal container.

8 Storage

Store at controlled room temperature.

Broncus Medical Inc.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.
!	Caution: consult instructions for use
STERILE | R	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
LOT	Serial number or batch code
	Use before
2	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Appendix E: Predicate 510(k)Summaries

Summaries for the following devices are included,

1. LungPoint Software with FlexNeedle
2. inReach System
3. CRE Pulmonary Balloon Dilatation Catheter

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Broncus Technologies, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

OCT 12 2011

Re: K112051
Trade/Device Name: LungPoint™ Planning and Virtual Brochoscopic Navigation (VBN) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 3, 2011
Received: October 6, 2011

Dear Mr. Job:

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

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112051

Device Name: LungPoint™ Planning and Virtual Bronchoscopic Navigation (VBN) Software

Indications for Use: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112051 Page __ of ___

K110093

FEB 1 1 2011

510(k) SUMMARY
superDimension® Marker Delivery Kit

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	superDimension, Ltd.
Address	8 Hamenofim St. P.O. Box 2045 Herzliya 46120 Israel
Phone number	+972-(0)9-971-3700
Fax number	+972-(0)9-971-3701
Establishment Registration Number	3004659744
Name of contact person	Jonathan Kovach Vice President, Quality and Regulatory Affairs 763-210-4000
Date prepared	01/10/2011
Name of device	
Trade or proprietary name	superDimension i·Logic inReach System superDimension inReach System superDimension/Bronchus
Common or usual name	Bronchoscope
Classification name	Computed tomography x-ray system
Classification panel	Radiology
Regulation	21 CFR Part 892.1750
Product Code(s)	JAK
Legally marketed device(s) to which equivalence is claimed	superDimension i·Logic inReach System, K071473/K092365/K102604
Reason for 510(k) submission	Introduction of accessory Marker Delivery Kit for the placement of markers into soft lung tissue using the superDimension i·Logic inReach System.
Device description	The superDimension i·Logic inReach System is a device that guides a bronchoscope and endoscopic tools to a target in or adjacent to the bronchial tree on a path identified by CT scan. The superDimension i·Logic inReach System also allows visualization of the target and the interior of the bronchial tree; placement of catheters in the bronchial tree; and placement of radiosurgical and dye markers into soft lung tissue to guide radiosurgery and thoracic surgery.
Intended use of the device	Enable the diagnosis and treatment of lung cancer.

dications for use	Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	Comparison to New Device
Indications for Use	Same
Anatomical Sites	Same
Basic Principle	Same
Localization Methodology	Same
Visualization Principle and Method of Visualization of Path and Organs	Same
Display Methods	Same
Interventional Instrument	Same. Accessory Marker Delivery Kit is being added.
Method of tracking location	Same
Computer function and type	Same
Energy Released into Body (Negligible)	Same
Compatibility with other devices	Same. Accessory Marker Delivery Kit is being added.
.ocompatibility	Same. Accessory Marker Delivery Kit is being added.
Medical electrical equipment safety compliance	Same
Registration Modes and Navigation Guidance	Same
Software	Same
Sterile Accessories	Same. Accessory Marker Delivery Kit is being added.
Marker Placement	Same. Accessory Marker Delivery Kit is being added.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

The superDimension Marker Delivery Kit and Instructions for Use were subjected to the superDimension design control process. Risk Management was performed to analyze the potential hazards associated with the changes. Appropriate design verification and validations were performed to assure the superDimension i·Logic inReach System continues to be safe and effective for its intended use.

Comparative Performance Information Summary

Not Required to validate the changes to the superDimension System.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical tests were not required to validate the changes to the superDimension System.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The superDimension i·Logic inReach System with the accessory Marker Delivery Kit is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

superDimension, Ltd.
% Mr Jonathan Kovach
Vice President, Quality and Regulatory Affairs
superDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPOLIS MN 55441

FEB 1 1 2011

Re: K110093
Trade/Device Name: superDimension® Marker Delivery Kit
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 10, 2011
Received: January 12, 2011

Dear Mr. Kovach:

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

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110093

Device Name: superDimension® Marker Delivery Kit

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110093

K023337

NOV 1 8 2002

SECTION 14

510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(I)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

Date:	October 4, 2002
Common/Usual Names:	Balloon Dilatation Catheter
Trade/Proprietary Names:	CRE™ Pulmonary Balloon Dilatation Catheter
Classification Name & Device Classification:	Class II

Name	Number	21CFR Ref.
Bronchoscope & Acc.	77 KTI	874.4680

Device Panel/Branch:	Ear, Nose and Throat (ENT)
Owner/Operator:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
Contact Person:	Paige Sweeney Regulatory Affairs Specialist

Description of Devices

The CRE™ Pulmonary Balloon Dilatation Catheter is used to access the airway tree via a bronchoscope for the purpose of dilating strictures. It consists of an inflatable balloon on a catheter shaft with lumens for inflation and guidewire.

Indications for Use

The CRE™ Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.

Descriptive and Technological Characteristics of Proposed and Predicate Devices

Boston Scientific Corporation believes that the CRE™ Pulmonary Balloon Dilatation Catheter is substantially equivalent to the currently marketed CRE™ Balloon Dilatation Catheter. The major components of these devices are the balloon, catheter shaft, and proximal hub. A thorough comparison of the descriptive characteristics between the proposed devices and the predicate devices show equivalence.

Conclusion

Boston Scientific Corporation has demonstrated that the CRE™ Pulmonary Balloon Dilatation Catheter is substantially equivalent to the currently marketed CRE™ Balloon Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2002

Boston Scientific, Corp.
c/o Paige Sweeney
Regulatory Affairs Specialist
Microvasive Endoscopy
One Boston Scientific Place
Natick, MA 01760

Re: K023337
Trade/Device Name: CRE™ Pulmonary Balloon Dilation Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: October 4, 2002
Received: October 7, 2002

Dear Ms. Sweeney:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SECTION 3
INDICATIONS FOR USE

510(k) Number: To Be Determined K023337

Device Name: - CRE™ Pulmonary Balloon Dilatation Catheter

Indication for Use: **The CRE™ Pulmonary Balloon Dilatation Catheter** is intended to be used endoscopically to dilate strictures of the airway tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21CFR 801.1091) **(Optional Format 1-2-96)**

Karen A Baker

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K023337

Appendix F: Shelf-life Protocol

(b)(4) Testing

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Appendix G: Biocompatibility Report QT-00804-R_A

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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 11737-1 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-326	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11737-1 Sterilization of medical devices - Microbiological methods - Part 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative references, Terms and definitions	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality managemetn system elements	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Selection of product	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

* 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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Form 3654 cont'd
Standard Title: ISO 11737-1 Sterilization of medical devices - Microbiological methods - Part 1

(b)(4)

Appendix I: FDA Forms 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11737-2 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, valida

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-327	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11737-2 Sterilization of medical devices - Microbiological methods - Part 2

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative references, Terms and definitions	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality management system elements	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Selection of product	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

* 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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Form 3654 cont'd
Standard Title: ISO 11737-2 Sterilization of medical devices - Microbiological methods - Part 2

(b)(4)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

11137-2: Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-225	
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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11607-1: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems ...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-355	
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]

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11607-1: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems ...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Normative References, Terms and Definitions, General requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Materials and preformed sterile barrier system	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6, 7	Design and development requirements for packaging system, information ...	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1: Biological Evaluation of medical devices: Part 1: Evaluation and 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?	☒	☐
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: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1: Biological Evaluation of medical devices: Part 1: Evaluation and testing within a risk management process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Normative References, Terms and Definitions, General Principles	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Categorization of Medical Devices	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
The LungPoint Tools are external communicating devices with limited (<24 hours) tissue contact per Section 5.2.2 and 5.3.

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6, 7	Biological Evaluation, Interpretation of Biological Evaluation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5: Biological Evaluation of medical devices: Part 5: Test for in vitro cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
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: _____

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[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 10993-5: Biological Evaluation of medical devices: Part 5: Test for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative References, Terms and Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5, 6	Sample and control preparation, cell lines, culture medium	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Preparation of cell stock culture, Test procedures, Test reports, Results	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Qualitative evaluation was conducted (Section 8.5.1)

DESCRIPTION
NA

JUSTIFICATION
NA

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10: Biological Evaluation of medical devices: Part 10: Tests for irritation and skin sensitization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-174	
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.

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[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 10993-10: Biological Evaluation of medical devices: Part 10: Tests for irritation and skin sensitization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Normative References, Terms and Definitions, General Principles	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Pretest consideration	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Section 6.4 - Animal intracutaneous (intradermal) reactivity test was followed

DESCRIPTION
NA

JUSTIFICATION
NA

* 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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Paperwork Reduction Act Statement

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Form 3654 cont'd
Standard Title: ISO 10993-10: Biological Evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

(b)(4)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-11: Biological evaluation of medical devices - Part 11: Tests for systemtic toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-176	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance:

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-11: Biological evaluation of medical devices - Part 11: Tests for systemtic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Normative references, Terms and definitions, General considerations	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Acute Systemic Toxicity	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Repeated exposure systemic toxicity	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10555-1: Sterile, Single-use Intravascular Catheters - Part 1: General Requirements (Amendment 2)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-355	
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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10555-1: Sterile, Single-use Intravascular Catheters - Part 1: General Requirements (Amendment 2)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative References, Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Sections 4.1, 4.2, and 4.5 were followed.

DESCRIPTION
These sections refer to general requirements, biocompatibility and force at break.

JUSTIFICATION
ISO 10555 is specific to intravascular catheters and, thus, is not required for bronchoscopic devices. Therefore only the applicable sections were followed.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5, 6	Description of nominal size, Information to be supplied by the manufacturer	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
NA

DESCRIPTION
NA

JUSTIFICATION
ISO 10555 is specific to intravascular catheters and, thus, is not required for bronchoscopic devices. Therefore compliance with only part of the standard is acceptable.

* 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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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

BS EN 1618: Catheters other than intravascular catheters - Test methods for common properties

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

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
BS EN 1618: Catheters other than intravascular catheters - Test methods for common properties

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2, Annex A to F,ZA	Test Methods and Results	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Annex B was followed to test methods for tensile property testing. Other appendices were not followed

DESCRIPTION
Annex B is the only annex applicable to the LungPoint Tools.

JUSTIFICATION
The applicable annex was followed for tensile property testing.

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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newborns hospitalized at this institution, including full access to the child, decision making authority for health care and other matters, and discharge of the child directly to them, and shall refer to them as parents of this child in any pertinent documents. Further, that the child's medical records shall be made available to Mahtab Fatemi or Bernard J.H. Verwer upon her or his request without the need for further consent or authorization from any other entity;

7. The Ohio Division of Vital Records shall prepare the birth certificate consistent with this order, that is, the Division of Vital Records shall prepare the birth certificate of the child delivered by Melissa Wilcox on or about July 30, 2013 by referencing only the names and appropriate information of the judicially - declared legal parents, Mahtab Fatemi and Bernard J.H. Verwer;
8. Good cause exists to deem this case confidential and sealed from the public; a(b)(6) y, this Court orders that no person may examine the court file except the Parties and any attorney appoint by said Parties to act on their behalf and,
9. Such other and further relief as the nature of this cause may require.

_____
Mahtab Fatemi,

_____
Bernard J.H. Verwer

_____
Melissa Wilcox (b)(4)

_____
Michael Wilcox

_____
JUDGE

(b)(6)

(b)(6)

Broncus Medical, Inc.
1400 N. Shoreline Blvd.
Suite A8
Mountain View, CA 94043
www.broncus.com

(650) 428-1600
(650) 428-1542 fax

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

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Attachment 1: CDRH Form 3564

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

FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Broncus Medical Inc

Establishment Registration Number: 3007867778

Division Name *(if applicable)*

Phone Number *(including area code)*: 650-428-1600

Street Address: 1400 N Shoreline Blvd, A8

FAX Number *(including area code)*: 650-428-1542

City: Mountain View

State / Province: CA

ZIP Code: 94043

Country: USA

Contact Name: John Magnasco

Contact Title: VP, Operations and Quality Assurance

Contact E-mail Address: jmagnasco@broncus.com

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

[redacted]

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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

Attachment 2: Indications for Use

Indications for Use

510(k) Number (if known): K_____

Device Name: LungPoint Tools - LungPoint Dilation Balloon and LungPoint Sheath

Indications for Use: The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ___ of ___

Attachment 3: Instructions for Use LungPoint Sheath

Broncus Medical Inc.

LungPoint™ Sheath

REF **Catalog number 10007**

Instructions For Use (IFU)

Table of Contents

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs.

The sheath enables physicians to easily access targets and allows for multiple approaches to the preselected target. It allows for the repeated placement of endoscopic tools to a specified lesion(s) during one procedure. The sheath is provided with a stylet, which is used to minimize the amount of airway mucosa entering the sheath's lumen and/or to provide rigidity (i.e. pushability).

The sheath (with stylet, if necessary) is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools. Once placed, other endoscopic tools, such as needles, dilation balloons, or other endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. If a stylet is used, it must be removed prior to the introduction of the other tools.

The LungPoint Sheath is comprised of a braid reinforced tubing,to resist kinking with articulation along with an incorporated stylet. The stylet when mated, provides for a rounded tip during insertion and pushability for navigation to the target. Removal of the stylet allows for standard 2.0mm working channel bronchoscopic accessories to be used though the lumen of the sheath. The tip of the Sheath is marked visually with black bands at the tip and in 10mm increments to 60mm to provide the user with an indication of the traveled depth during insertion. Also included are multiple radiopaque marker bands at the distal end at the tip, 5mm, 10mm and 20mm to aid visualization of the sheath under fluoroscopy.

Product Configuration and Dimensions

The LungPoint Sheath (see illustration in Figure 1) has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

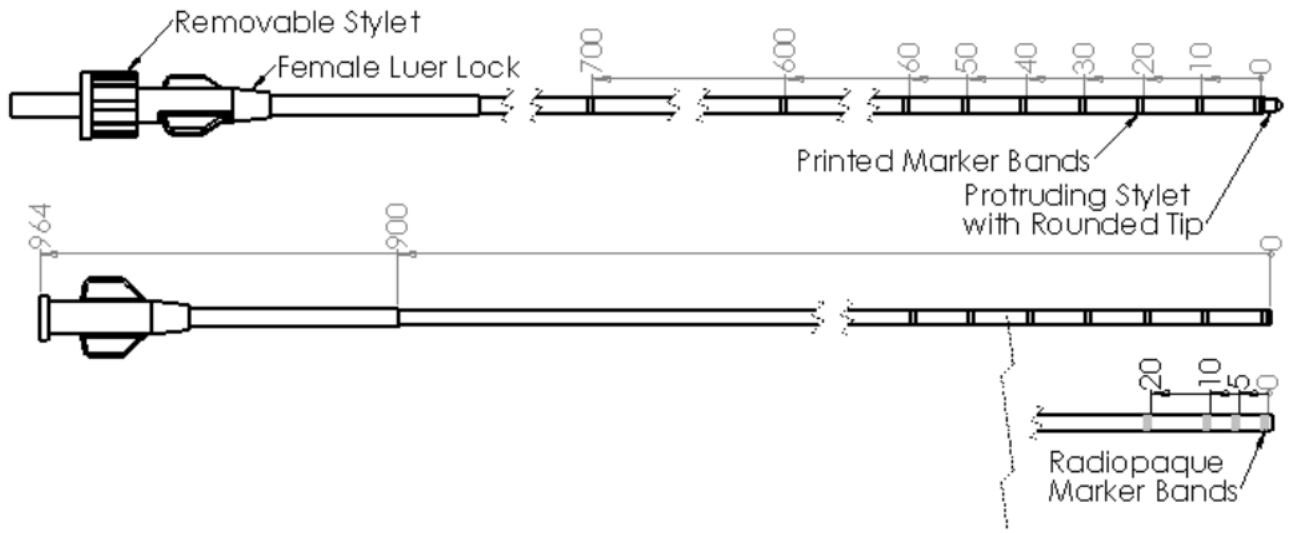


Figure 1: LungPoint Sheath

2 Intended Use

The LungPoint Sheath is part of the LungPoint Tools, which are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

3 Contraindications

There are no known contraindications.

⚠ WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Sheath should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- DO NOT activate active devices (e.g., electrosurgical devices) inside the lumen of the sheath. The active portion of the device must be extended beyond the sheath prior to activation.
- While advancing the sheath, DO NOT USE excessive force as this may advance the device in an uncontrolled manner that could result in harm to the patient's airway wall and cause bleeding.
- The LungPoint Sheath should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Sheath in contradiction to the instructions may harm the device, bronchoscope or patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

6.1 Materials Required

- LungPoint Sheath
- Luer-lock aspiration syringe
- Flexible bronchoscope with a working channel of 2.8 mm or greater

6.2 Device Inspection and Preparation

6.2.1 Read all IFUs, package inserts, labels, and warnings for the device before beginning the procedure.

CAUTION: **Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.**

6.2.2 Aseptically remove the LungPoint Sheath from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: **If any damage or irregularity is found,** DO NOT USE **the device as this could result in harm to the patient.**

CAUTION: DO NOT USE **the device past its "Use Before" (expiration) date.**

6.2.3 Before inserting the device into the working channel of the bronchoscope, verify that the stylet is secured to the sheath via the luer lock connection.

7 Operating Instructions

7.1 Carefully advance the Sheath through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 For accessory use: remove the stylet by loosening the luer lock connection and withdraw the stylet. Insert the accessory device into the lumen.

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the sheath, accessory or bronchoscope.

7.4 If using fluoroscopy – visualize radiopaque accessory devices position relative to the tip marker band.

7.5 Withdraw the Sheath from the bronchoscope.

7.6 At the completion of the patient procedure, dispose of the device in accordance with applicable hospital, local, state and federal laws and regulations.

8 Storage

Store at controlled room temperature.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Caution: consult instructions for use
	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
	Serial number or batch code
	Use before
	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Attachment 4: Instructions for Use LungPoint Dilation Balloon

Broncus Medical Inc.

LungPoint™ Dilation Balloon

REF **Catalog number 10008**

Instructions For Use (IFU)

Table of Contents

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or other endoscopic tool, such as a sheath, and is used to dilate lung tissue. The balloon may be used during interventional bronchoscopy procedures as determined by the physician performing the bronchoscopy.

The LungPoint Dilation Balloon is comprised of a catheter with a non-compliant 4mm OD x 6mm long inflatable balloon at the distal end and a y-connector with female luer fittings at the proximal end. The side port of the Y connector is used for inflation and deflation of the balloon with a standard indeflator capable of 12atm pressure (typically with a gage) and a male luer lock connector. The center port contains a nitinol wire which is fixed in place for pushability and kink resistance during tortuous bronchoscopic navigation. Included are two radiopaque marker bands and the distal and proximal ends of the balloon inflation length for visualization of the device position under fluoroscopy

Product Configuration and Dimensions

The LungPoint Dilation Balloon (see illustration in Figure 1) has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

2 Intended Use

The LungPoint Dilation Balloon is part of the LungPoint Tools, which are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs.

3 Contraindications

There are no known contraindications.

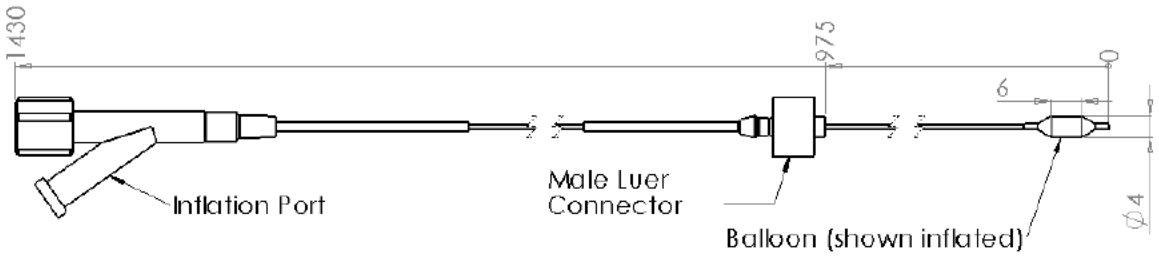


Figure 1: Dilation Balloon (shown inflated)

⚠ WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Dilation Balloon should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- The LungPoint Dilation Balloon should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Dilation Balloon in contradiction to the instructions may harm the device, bronchoscope or patient.
- The rated burst pressure is 20 atmosphere, exceeding the rated burst pressure may result in harm to the patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

6.1 Materials Required

- LungPoint Dilation Balloon
- Indeflator capable of 12atm
- Flexible bronchoscope with a working channel of 2.0 mm or greater

6.2 Device Inspection and Preparation

6.2.1 Read all IFUs, package inserts, labels, and warnings for the LungPoint Dilation Balloon before beginning the procedure.

CAUTION: Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.

6.2.2 Aseptically remove the LungPoint Dilation Balloon from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: If any damage or irregularity is found, **DO NOT USE** the device as this could result in harm to the patient.

CAUTION: DO NOT USE the device past its “Use Before” (expiration) date.

CAUTION: DO NOT place or manipulate the catheter in the airways unless under direct visualization with a bronchoscope or using fluoroscopy as this may result in harm to the patient.

7 Operating Instructions

7.1 Carefully advance the balloon through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 Connect the indeflator via the luer lock connector and inflate to 10atm. Do not exceed the rated burst pressure of 20 atm.

7.4 If using fluoroscopy – visualize balloon inflation location via the radiopaque marker bands and the distal and proximal ends of the balloon inflation length.

7.5 Deflate the balloon, and remove the device

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the device or bronchoscope.

7.6 At the completion of the patient procedure, dispose of the device in accordance with applicable hospital, local, state and federal laws and regulations.

8 Storage

Store at controlled room temperature.

Broncus Medical Inc.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.
!	Caution: consult instructions for use
STERILE | R	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
LOT	Serial number or batch code
	Use before
2	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Attachment 5: 510(k) Summary

510(k) Summary

1. Date of Summary

April 3, 2013

2. 510(k) Applicant

Broncus Medical, Inc.
1400 N. Shoreline Blvd, Suite A8
Mountain View, California 94043
Phone: (650) 428-1600
FAX: (650) 428-1542

Contact Person: Gary Kaplan
Phone: (650) 428-1600
Fax: (650) 428-1542
e-mail: gkaplan@broncus.com

3. Device Overview

Trade Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)

Common Name: Sheath and Dilation Balloon

Classification Name: Bronchoscope and Accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System (with FlexNeedle)	Broncus Technologies, Inc*	K112051, cleared to market on October 12, 2011 (and K093423, K091160 and K090095, by reference)
inReach System	SuperDimension	K110093, cleared to market on February 11, 2011 (and K071473, K092365 and K102604, by reference)
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002

*NOTE: Broncus Technologies, Inc changed their name to Broncus Medical, Inc in June 2012.

5. Device Description

The LungPoint Tools are endoscopic tools used during bronchoscopy procedures. The LungPoint Sheath is designed to be used with a bronchoscope to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted lung tissue within the respiratory organs. It is advanced to a predefined target following guidance of the LungPoint Software. The LungPoint Dilation Balloon is used to dilate tissue of the bronchial tree and may be inserted through the sheath or directly through the working channel of the bronchoscope. Additionally, both devices could be used without the LungPoint Software.

The materials used in the LungPoint Tools are commonly used medical grade materials and include platinum iridium markers.

6. Intended Use

The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

7. Comparison to Predicate Device

The LungPoint Tools are commonly used endoscopic tools with the same technological characteristics as the predicate devices. The indications for use of the LungPoint Tools for use with the LungPoint Software all within the intended use of the predicate device, which is to enable treatment and diagnosis of lung cancer. The technological characteristics of the subject devices are the same as those of the predicate devices. Performance of the subject devices has been verified by use of accepted methods.

8. Performance Data

The design and safety of the LungPoint Tools were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use. Testing included the following:

- Dimensional testing
- Joint/tensile test
- Simulated use
- Balloon fatigue/burst pressure
- Radiopacity.

9. Safety and Effectiveness

The LungPoint Tools labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the devices. The biocompatibility assessment of all patient contacting materials was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices*. In addition, the devices are sterilized using e-beam sterilization.

10. Conclusion

Based on the nonclinical testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

Attachment 6: Section 11 – Device Description

11. DEVICE DESCRIPTION

The LungPoint Sheath and LungPoint Dilation Balloon are endoscopic tools, which are intended to be used as accessories to the LungPoint Software. They are described in more detail in Sections 11.1 and 11.2, respectively. The LungPoint Software may be used with these tools or other commercially available tools. However, these tools have been specifically designed to be used with the Software but can be used without the LungPoint Software, as well.

11.1. LungPoint Sheath

The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs.

The sheath enables physicians to easily access targets and allows for multiple approaches to the preselected target. It allows for the repeated placement of endoscopic tools to a specified lesion(s) during one procedure. (b)(4) [redacted] (b)(4)

The sheath (b)(4) [redacted] is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools, such as the dilation balloon described in the next section. Once placed, other endoscopic tools, such as needles, dilation balloons, or other endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. If a stylet is used, it must be removed prior to the introduction of the other tools.

The LungPoint Sheath is provided as a sterile device for single use and is available in one size. A detailed drawing of the sheath is provided in **Appendix B.**

11.1.1. Materials

The materials used in the sheath are outlined below. All materials passed appropriate biocompatibility requirements as outlined in **Section 16**.

Table 11.1.1-1: LungPoint Sheath Materials List

Material Use	Material Description	Common Name
(b)(4) [redacted]		

Material Use	Material Description	Common Name
(b)(4)		

(b)(4)

Supporting information on the (b)(4) is included in **Appendix C2** as outlined below.

Supporting Information
Material Safety Data Sheet (MSDS)
(b)(4)

11.1.2. Performance Specification

Performance specification of the device, acceptance criteria and rationale for the acceptance criteria for each specification to ensure safe and effective use are outlined below.

Table 11.1.2-1: LungPoint Sheath Performance Specifications (D0210-007_B)

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
Dimensional Testing	(b)(4)	NA – all criteria are per the product specifications	(b)(4)

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
	(b)(4)		(b)(4)
Joints/ Tensile Test		Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995	
Simulated Use		NA – validated test fixture	

Performance Specification	Objective	Applicable Standards	Acceptance Criteria (confidence/reliability parameters)
	(b)(4)		(b)(4)
Radiopacity		NA	

11.2. LungPoint Dilation Balloon

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or sheath and is used to dilate lung tissue. The balloon may be used (b)(4) (b)(4) as determined by the physician performing the bronchoscopy.

The LungPoint Dilation Balloon is provided in one size, as outlined, and is a sterile device for single use.

Balloon Size (OD x length)	Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
(b)(4)			

When inflated at (b)(4) (diameter x length). A detailed drawing of the LungPoint Dilation Balloon is provided in **Appendix B**.

The materials used in the dilation balloon are outlined below.

Table 11.2-1: LungPoint Dilation Balloon Materials List

Material Use	Material Description	Trade Name
(b)(4)		

Material Use	Material Description	Trade Name
(b)(4)		

Performance specification of the device and acceptance criteria for each specification to ensure safe and effective use are outlined below.

Table 11.2-2: LungPoint Balloon Performance Specifications (D0210-007 B)

Test Title	Objective	Applicable Standards	Acceptance Criteria
Dimensional Testing	(b)(4)	NA – all criteria are per the product specifications	(b)(4)
Joints/ Tensile Test		Method: EN1618:1997 Acceptance Criteria: adapted from ISO 10555-1:1995	
Simulated Use		NA – validated test fixture	

Test Title	Objective	Applicable Standards	Acceptance Criteria
			(b)(4) [redacted]
Balloon burst pressure	(b)(4) [redacted]	NA	
Radiopacity	(b)(4) [redacted] y (b)(4) [redacted]	NA	

Attachment 7: Section 12 – Substantial Equivalence Discussion

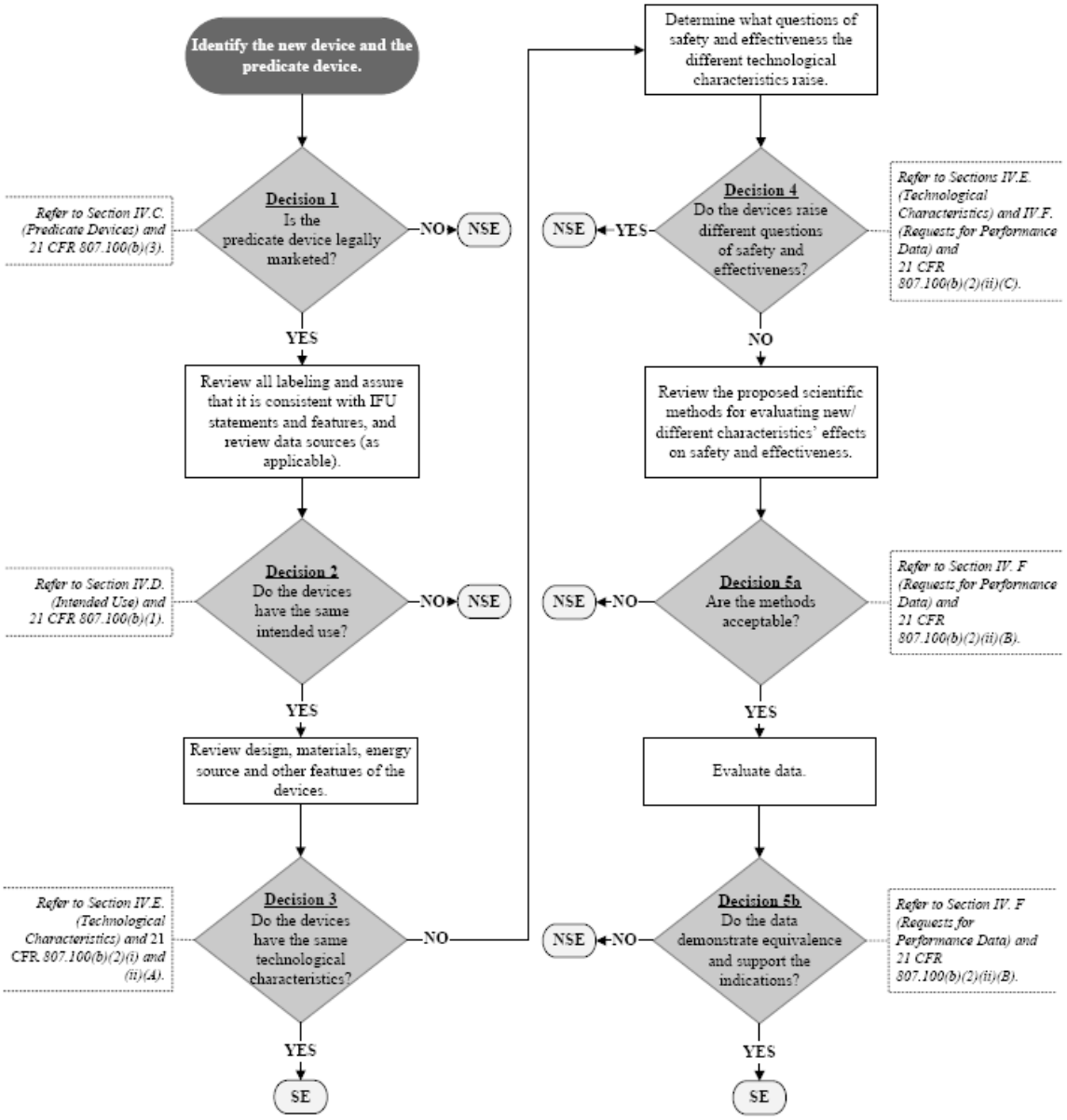
(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document



SE = "Substantially Equivalent"
NSE = "Not Substantially Equivalent"

This Flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.

Figure 1: 510(k) "Substantial Equivalence" Decision-Making Flowchart

Attachment 8: Pouch and Package Labels

Broncus Medical Inc.

Part No: # (b)(4)
Rev: (b) Draft

RELEASED

Label, Pouch, LungPoint Sheath

NOTE THAT THIS DOCUMENT IS ONLY FOR REVISION HISTORY OF 12198 IMAGE FILES

REVISION HISTORY – 12198 (CONTENT)

Rev	DCN #	Change Description	Release Date
(	[redacted]	Initial release	11/14/12

Label, Pouch, LungPoint Sheath

Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA 94043 USA
877-428-1600
www.broncus.com

LungPoint™ Sheath

REF 10007
QUANTITY 1

Sheath OD: 2.6 mm, Sheath ID: 2.0 mm
Working Length: 900 mm

LOT

Rx only

For single use. Sterility guaranteed if package unopened and undamaged. STERILE R

Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA 94043 USA
877-428-1600

P/N: 12198 Rev.A

See package insert for explanation of symbols.

REF 10007
LOT

REF 10007
LOT

Broncus Medical Inc.

Part No: #: (b)(4)
Rev: (b)

RELEASED

CONFIDENTIAL

Label, Pouch, LungPoint Dilation Balloon

NOTE THAT THIS DOCUMENT IS ONLY FOR REVISION HISTORY OF 12200 IMAGE FILES.

REVISION HISTORY – 12200 (CONTENT)

Rev	DCN #	Change Description	Release Date
(	(b)	Initial release	11/14/12

Broncus Medical Inc.

Part No: #: (b)(4)
Rev: (b)

RELEASED

CONFIDENTIAL

Label, Pouch, LungPoint Dilation Balloon

Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA 94043 USA
877-428-1600
www.broncus.com

LungPoint™ Dilation Balloon

REF 10008
QUANTITY 1

Inflated OD: 4 mm, Balloon Length: 6mm
Rated Burst Pressure:12 atm
Catheter OD: 1.0 mm
Working Length: 975 mm

LOT

℞only

For single use. Sterility guaranteed if package unopened and undamaged.

STERILE R

Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA 94043 USA
877-428-1600

P/N: 12200 Rev.A

See package insert for explanation of symbols.

REF 10008
LOT

REF 10008
LOT

Attachment 9: LungPoint Tools Addendum

LungPoint Software with Endoscopic Tools
Instructions for Use Addendum
DRAFT

LungPoint Overview

The LungPoint Software is a device that guides a bronchoscope and endoscopic tools to a prespecified target in or adjacent to the bronchial tree by providing a path which is displayed on a 3D reconstruction of CT scan. The Software allows for visualization of the target in the lung tissue or in the bronchial tree; visualization of the interior of the bronchial tree; placement of catheters in the bronchial tree; and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery. The LungPoint Software is intended to be used with various commercially available endoscopic tools.

Consult the LungPoint Software User Manual for detailed information about LungPoint.

LungPoint Tools

Broncus Medical provides the following endoscopic tools (referred to as LungPoint Tools) for use during Virtual Bronchoscopic Navigation. A brief description of each tool follows the table. The LungPoint Tools are ebeam sterilized, supplied sterile, for single patient use.

LungPoint Tool	Part Number	Description
FlexNeedle	10005	18 gauge
LungPoint Dilation Balloon*	TBD	Diameter x length: 4 x 6 mm Catheter length: 143 cm
LungPoint Sheath*	TBD	ID/OD: 2.0/2.6 cm Catheter length: 975 mm

*NOTE: The LungPoint Sheath and Balloon are for use with the LungPoint Software only.

FlexNeedle
The FlexNeedle is an aspiration needle commonly used to collect specimens for histophatology or cytopathology. The needle has a coring needle tip in a protective sheath that is designed to fit down the 2-mm working channel of a standard flexible optical bronchoscope. The needle tip is welded to a coil tube that comprises a flexible shaft, allowing the needle to bend with the bronchoscope articulation and enabling access to hard-to-reach locations. When used together with the LungPoint Software, the needle can be safely guided to a prespecified targeted area within the respiratory organs in order to collect specimens.

LungPoint Dilation Balloon
The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or sheath and is used to dilate lung tissue. The balloon may be used during interventional bronchoscopy procedures as determined by the physician performing the bronchoscopy.

LungPoint Sheath
The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs.

The sheath (with stylet, if necessary) is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools, such as the dilation balloon described in the previous section. Once placed, other endoscopic tools, such as needles, dilation balloons, or other endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. If a stylet is used, it must be removed prior to the introduction of the other tools.

WARNINGS AND CAUTIONS: LungPoint Tools

- The LungPoint Tools are supplied sterile and for single use only. Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.
- If any damage or irregularity is found to the device after opening, DO NOT USE the device as this could result in harm to the patient.
- DO NOT USE the device past its "Use Before" (expiration) date.
- Consult the individual instructions for use of the LungPoint Tools for additional warnings and cautions.

Attachment 10: Updated Shelf-life Protocol

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Attachment 11: Section 18 – Bench Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Attachment 12: (b)(4) Drawing

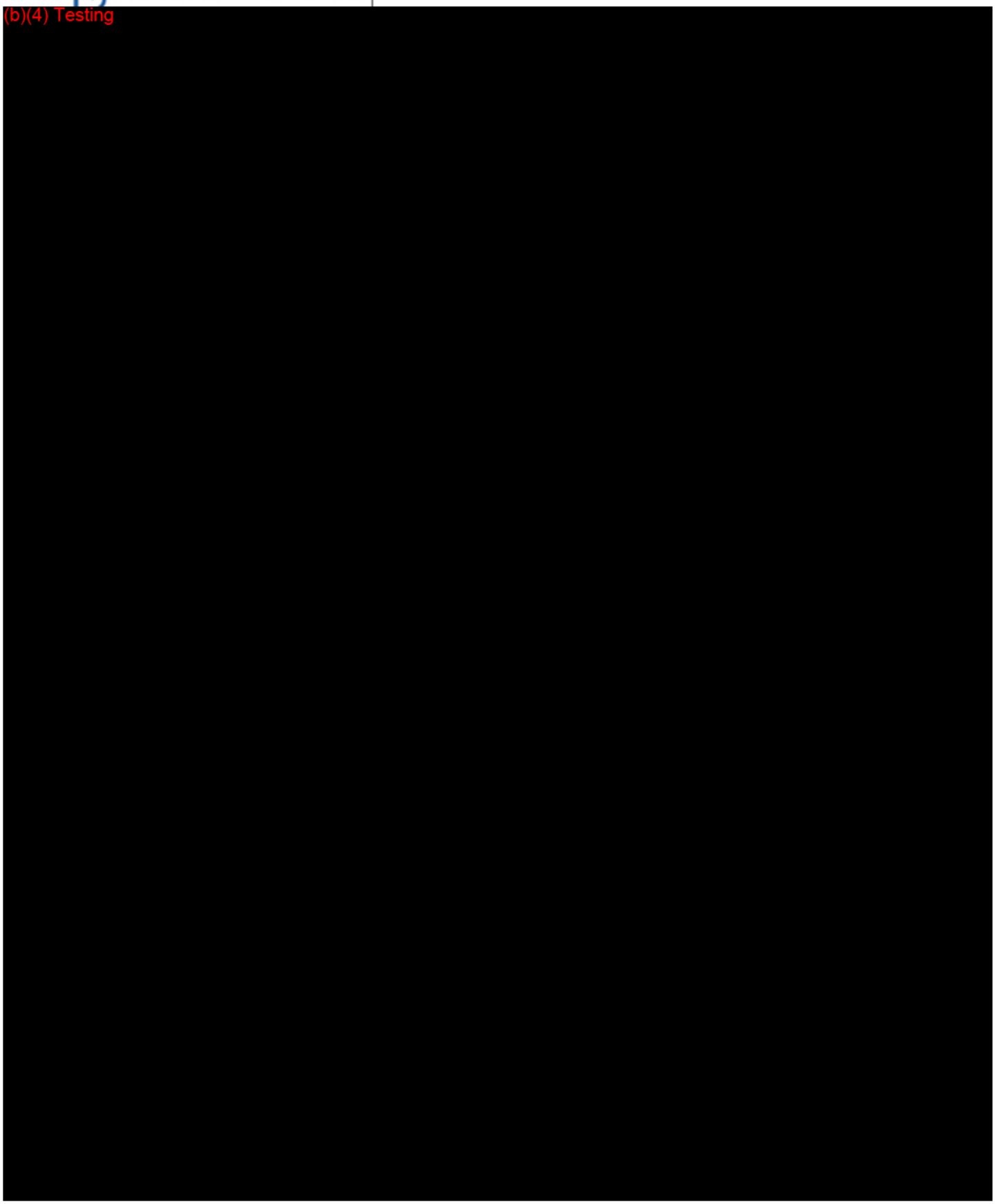
Sche

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

Attachment 13: Simulated Use Testing Flowchart (b)(4) Testing

(b)(4) Testing



Flowchart 1

Attachment 14: Predicate Device Labeling

Included in this attachment are the following,

1. Marketing Literature for the inReach System Components and Tools
2. K110093 inReach System
3. K102604 inReach System
4. Product Label for CRE Balloon

Components & Tools

superDimension leads the Electromagnetic Navigation Bronchoscopy™ (ENB) market with its i·Logic System. Designed to enable physicians to reach distant lung lesions in a minimally invasive manner, the i·Logic System consists of intuitive software and proprietary hardware.

i·Logic Components

Planning & Navigation Software

- A disposable Extended Working Channel (EWC) that extends beyond the reach of the bronchoscope and becomes a channel for endobronchial tools to distal locations in the lungs and mediastinum
- A disposable Locatable Guide (LG) that contains a **location sensor** at its distal tip and allows 360 degree steerability through the bronchial tree
- **Planning and navigation software**, providing physicians with a reconstruction of the bronchial airways of the lungs as well as tracking and localization through Electromagnetic Navigation Bronchoscopy™ (ENB).

Tools

The superDimension superTrax™ tools are the only tools specifically designed for use with the i·Logic System. These sterile single use tools feature flexible shaft designs for maximum trackability through distal airways.

Ordering Information for i-Logic™ Tools

DESCRIPTION	DIAMETER (mm)	WORKING LENGTH (cm)	REQUIRED WORKING CHANNEL (mm)	UNIT
Biopsy Forceps	1.7	110	2.0	5 / box
Cytology Brushes	1.7	120	2.0	10 / box
21g Aspirating Needles	1.8	130	2.0	5 / box

Ordering Information for i-Logic™ System and Components

DESCRIPTION
i-Logic™ System
i-Logic™ All-Inclusive Olympus® Procedure Kit
i-Logic™ All-Inclusive Pentax® Procedure Kit
i-Logic™ All-Inclusive Fujinon® Procedure Kit
i-Logic™ Steerable Navigation Catheter (LG)
i-Logic™ Guide Catheter (EWC)
Fujinon® Bronchoscope Adaptor
Olympus® Bronchoscope Adaptor
Pentax® Bronchoscope Adaptor
Bronchoscope Clip
Patient Sensor Patches (box of 60)

K110093

FEB 1 1 2011

510(k) SUMMARY
superDimension® Marker Delivery Kit

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	superDimension, Ltd.
Address	8 Hamenofim St. P.O. Box 2045 Herzliya 46120 Israel
Phone number	+972-(0)9-971-3700
Fax number	+972-(0)9-971-3701
Establishment Registration Number	3004659744
Name of contact person	Jonathan Kovach Vice President, Quality and Regulatory Affairs 763-210-4000
Date prepared	01/10/2011
Name of device	
Trade or proprietary name	superDimension i·Logic inReach System superDimension inReach System superDimension/Bronchus
Common or usual name	Bronchoscope
Classification name	Computed tomography x-ray system
Classification panel	Radiology
Regulation	21 CFR Part 892.1750
Product Code(s)	JAK
Legally marketed device(s) to which equivalence is claimed	superDimension i·Logic inReach System, K071473/K092365/K102604
Reason for 510(k) submission	Introduction of accessory Marker Delivery Kit for the placement of markers into soft lung tissue using the superDimension i·Logic inReach System.
Device description	The superDimension i·Logic inReach System is a device that guides a bronchoscope and endoscopic tools to a target in or adjacent to the bronchial tree on a path identified by CT scan. The superDimension i·Logic inReach System also allows visualization of the target and the interior of the bronchial tree; placement of catheters in the bronchial tree; and placement of radiosurgical and dye markers into soft lung tissue to guide radiosurgery and thoracic surgery.
Intended use of the device	Enable the diagnosis and treatment of lung cancer.

dications for use	Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	Comparison to New Device
Indications for Use	Same
Anatomical Sites	Same
Basic Principle	Same
Localization Methodology	Same
Visualization Principle and Method of Visualization of Path and Organs	Same
Display Methods	Same
Interventional Instrument	Same. Accessory Marker Delivery Kit is being added.
Method of tracking location	Same
Computer function and type	Same
Energy Released into Body (Negligible)	Same
Compatibility with other devices	Same. Accessory Marker Delivery Kit is being added.
.ocompatibility	Same. Accessory Marker Delivery Kit is being added.
Medical electrical equipment safety compliance	Same
Registration Modes and Navigation Guidance	Same
Software	Same
Sterile Accessories	Same. Accessory Marker Delivery Kit is being added.
Marker Placement	Same. Accessory Marker Delivery Kit is being added.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

The superDimension Marker Delivery Kit and Instructions for Use were subjected to the superDimension design control process. Risk Management was performed to analyze the potential hazards associated with the changes. Appropriate design verification and validations were performed to assure the superDimension i·Logic inReach System continues to be safe and effective for its intended use.

Comparative Performance Information Summary

Not Required to validate the changes to the superDimension System.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical tests were not required to validate the changes to the superDimension System.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The superDimension i·Logic inReach System with the accessory Marker Delivery Kit is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

superDimension, Ltd.
% Mr Jonathan Kovach
Vice President, Quality and Regulatory Affairs
superDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPOLIS MN 55441

FEB 1 1 2011

Re: K110093
Trade/Device Name: superDimension® Marker Delivery Kit
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 10, 2011
Received: January 12, 2011

Dear Mr. Kovach:

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

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110093

Device Name: superDimension® Marker Delivery Kit

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110093

510(k) Summary
superDimension, Ltd.
Special 510(k)
superDimension® i·Logic™ inReach® System
Addition of Edge™ Catheter System

OCT - 7 2010
K102604

Date Prepared:

09/07/2010

510(k) Applicant:

superDimension, Ltd.
8 Hamenofim St., P.O. Box 2045
Herzliya 46120
Israel
Ph: +972-(0)9-971-3700
Fax: +972-(0)9-971-3701

510(k) Application Correspondent:

Jonathan Kovach
Vice President, Quality and Regulatory Affairs
superDimension, Inc.
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441
Phone: 763-210-4015
Cell : 763-360-4984
Fax : 763-210-4098
Email : jkovach@superdimension.com

Name of Device :

Trade Name :	superDimension i·Logic inReach System superDimension inReach System superDimension/Bronchus
Common Name:	Bronchoscope
Classification Name:	Computed tomography x-ray system 21 CFR Part 892.1750 Product code JAK

Equivalent Legally-Marketed Device:

superDimension i·Logic inReach System, K071473/K092365

Description:

The superDimension i·Logic inReach System is a device that guides a bronchoscope and endoscopic tools to a target in or adjacent to the bronchial tree on a path identified by CT scan. The superDimension i·Logic inReach System also allows visualization of the target and the interior of the bronchial tree; placement of catheters in the bronchial tree; and placement of radiosurgical and dye markers into soft lung tissue to guide radiosurgery and thoracic surgery.

superDimension is introducing the Edge Catheter System for use with the superDimension i·Logic inReach System. The i·Logic inReach System accomodates both the Edge Catheter and the currently available inReach Catheter System.

Intended Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Summary of Characteristics Compared to Predicate Device:

The Edge Catheter System is an alternate catheter system for use with the superDimension i·Logic inReach System. The Edge Catheter System includes modifications to the existing inReach Catheter System, procedure software, and instructions for use. The Edge Catheter and inReach Catheter systems may both be used with the superDimension i·Logic inReach System. No changes are being made to the electromagnetic components or fundamental scientific technology of the i·Logic inReach System.

Performance Data:

The Edge Catheter System, i·Logic inReach Software, and Instructions for Use were subjected to the superDimension design control process. Risk Management was performed to analyze the potential hazards associated with the changes. Appropriate design verification and validations were performed to assure the superDimension i·Logic inReach System continues to be safe and effective for its intended use.

Clinical Data:

Clinical tests were not required to validate the changes to the superDimension inReach System.

Conclusion:

The superDimension i·Logic inReach System with the Edge Catheter is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

SuperDimension, Ltd.
% Mr. Jonathan Kovach
Vice President, Quality and Regulatory Affairs
161 Cheshire Lane, Suite 100
MINNEAPOLIS MN 55441

OCT - 7 2010

Re: K102604
Trade/Device Name: superDimension® i-Logic™ inReach® System with Edge™ Catheter
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 7, 2010
Received: September 10, 2010

Dear Mr. Kovack:

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

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medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

OCT - 7 2010

510(k) Number (if known): K102604

Device Name: superDimension® i·Logic™ inReach® System with Edge™ Catheter

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102604

CRE™ PULMONARY BALLOON DILATATION CATHETER

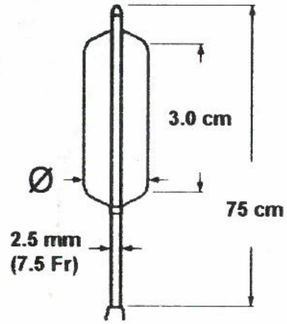
CE 0197

(1) CRE Pulmonary, Balloon Dilatation Catheter; Balloon O.D.:8-9-10mm; Balloon Length:3.0cm;.035in. (.89mm) x min 180cm Guidewire Compatible.
(1) CRE Pulmonal ballongdilatationskateter; ballong ytterdiameter: 8-9-10mm; Ballonglängd: 3,0cm; 0,035in. (0,89mm) x min 180cm kompatibla ledare.
(1) CRE Pulmonary, Ballon Dilatatie-catheter; Ballon-diameter: 8-9-10mm; Ballon-lengte: 3,0cm; 0.035in. (0,89mm) x min 180cm Geleidedraad-compatibel
(1) CRE pulmonaire, cathéter de dilatation à ballonnet ; Ø ext du ballonnet : 8 mm - 9 mm - 10 mm ; Longueur du ballonnet : 3.0 cm ; Compatible avec un fil guide de 0,035 in. (0,89 mm) x 180 cm minimum
(1) CRE Lungenkatheter, Ballondilatationskatheter; Ballon A. D.: 8-9-10 mm; Ballonlänge 3,0 cm; kompatibel zu einem 0.035in. (0,89 mm) x min 180 cm-Führungsdraht
(1) CRE polmonare, Catetere dilatatore a palloncino; Diam. est. palloncino: 8-9-10 mm; Lunghezza palloncino: 3,0 cm; 0,035 in. (0,89 mm) x min. 180 cm Compatibile con guida.
(1) Cateter de Dilatação por Balão Pulmonar CRE; D.E. do Balão: 8-9 - 10 mm; Comprimento do Balão: 3,0 cm; Fio-guia Compatível de 0,89 mm (0.035 in.) x 180 cm (min.).
(1) CRE pulmonar, catéter balón de dilatación; D.E. del balón: 8-9-10 mm; Longitud del balón: 3,0 cm; Guía compatible de 0,89 mm (0.035 in.) x 180 cm (min.).
(1) CRE pulmonar, ballondilatationskateter; ballonens udvendige diameter: 8-9-10mm; ballonens længde: 3,0 cm; kompatibel med 0,035 tommer (0,89mm) x min. 180cm ledetråd.
(1) CRE Πνευμονικός, Καθετήρας μπαλονιού διαστολής, Εξωτ. Διάμ. Μπαλονιού: 8-9-10 mm, Μήκος μπαλονιού: 3.0 cm, Συμβατό με οδηγό σύρμα 0.89 mm (0.035 in.) x 180cm το ελάχιστο

Order No./REF: **5033** **(M00550330)**

Use Before Date: **2006-10**

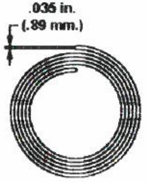
Lot Number: LOT **6995804**



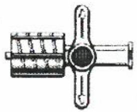
Ø mm (Fr)	8 (24)	9 (27)	10 (30)
ATM (PSI)	3 (44)	5.5 (81)	9 (132)

≤ 9 atm
Maximum Inflation Pressure

LATEX
Latex Free



Guidewire Compatible



STERILE EO

+M00550330-

+$$80110066995804-/

CRE is a Trademark of Boston Scientific Corporation. Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Boston Scientific
MICROVASIVE®
Customer Service 1-800-225-3226

REF 5033 (M00550330) CRE™ Pulmonary LOT 6995804	PATIENT CHARGE	REF 5033 (M00550330) CRE™ Pulmonary LOT 6995804	PATIENT CHART	REF 5033 (M00550330) CRE™ Pulmonary LOT 6995804	INVENTORY CONTROL

810095-07 Rev. B

90036749-04 REV. B
Made in Ireland

Distributed in USA By: Boston Scientific Corporation, One Boston Scientific Place Natick, MA USA 01760.
EU Authorized Representative: Boston Scientific International, 91 Boulevard National, 92257 La Garenne Colombes Cedex, France
Manufacturer: Boston Scientific Cork Ltd., Business and Technology Park, Model Farm Rd., Cork, Ireland.

Single Use Only
Read Instructions for Use

Attachment 1: Updated Instructions for Use LungPoint Dilation Balloon

Broncus Medical Inc.

LungPoint™ Dilation Balloon

REF **Catalog number 10008**

Instructions For Use (IFU)

Table of Contents

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or other endoscopic tool, such as a sheath, and is used to dilate lung tissue. The balloon may be used during interventional bronchoscopy procedures as determined by the physician performing the bronchoscopy.

The LungPoint Dilation Balloon is comprised of a catheter with a non-compliant 4mm OD x 6mm long inflatable balloon at the distal end and a y-connector with female luer fittings at the proximal end. The side port of the Y connector is used for inflation and deflation of the balloon with a standard indeflator capable of 12atm pressure (typically with a gage) and a male luer lock connector. The center port contains a nitinol wire which is fixed in place for pushability and kink resistance during tortuous bronchoscopic navigation. Included are two radiopaque marker bands and the distal and proximal ends of the balloon inflation length for visualization of the device position under fluoroscopy

Product Configuration and Dimensions

The LungPoint Dilation Balloon (see illustration in Figure 1) has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

2 Intended Use

The LungPoint Dilation Balloon is part of the LungPoint Tools, which are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

3 Contraindications

There are no known contraindications.

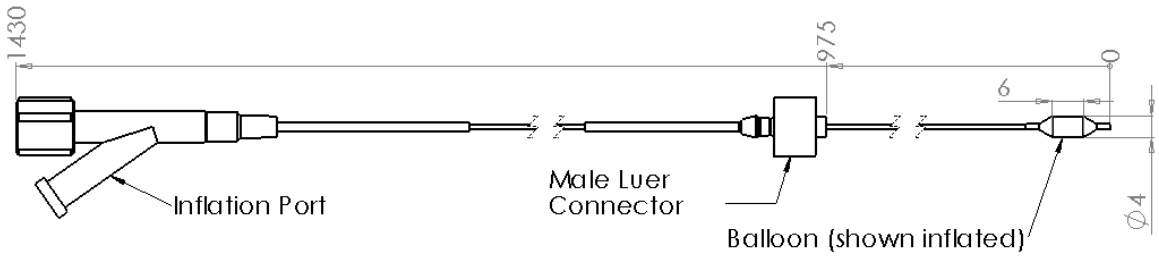


Figure 1: Dilation Balloon (shown inflated)

WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Dilation Balloon should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- The LungPoint Dilation Balloon should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Dilation Balloon in contradiction to the instructions may harm the device, bronchoscope or patient.
- The rated burst pressure is 20 atmosphere, exceeding the rated burst pressure may result in harm to the patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

6.1 Materials Required

- LungPoint Dilation Balloon
- Indeflator capable of 12atm
- Flexible bronchoscope with a working channel of 2.0 mm or greater

6.2 Device Inspection and Preparation

6.2.1 Read all IFUs, package inserts, labels, and warnings for the LungPoint Dilation Balloon before beginning the procedure.

CAUTION: Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.

6.2.2 Aseptically remove the LungPoint Dilation Balloon from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: If any damage or irregularity is found, **DO NOT USE** the device as this could result in harm to the patient.

CAUTION: DO NOT USE the device past its “Use Before” (expiration) date.

CAUTION: DO NOT place or manipulate the catheter in the airways unless under direct visualization with a bronchoscope or using fluoroscopy as this may result in harm to the patient.

7 Operating Instructions

7.1 Carefully advance the balloon through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 Connect the indeflator via the luer lock connector and inflate to 10atm. Do not exceed the rated burst pressure of 20 atm.

7.4 If using fluoroscopy – visualize balloon inflation location via the radiopaque marker bands and the distal and proximal ends of the balloon inflation length.

7.5 Deflate the balloon, and remove the device

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the device or bronchoscope.

7.6 At the completion of the patient procedure, dispose of the device in accordance with applicable hospital, local, state and federal laws and regulations.

NOTE: The LungPoint Dilation Balloon has been tested to three insertion cycles, meaning that the dilation balloon can be inserted/inflated/deflated/removed a total of three times and must be discarded after the third complete cycle.

8 Storage

Store at controlled room temperature.

Broncus Medical Inc.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Caution: consult instructions for use
	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
	Serial number or batch code
	Use before
	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Attachment 2: Updated 510(k) Summary

510(k) Summary

1. Date of Summary

April 22, 2013

2. 510(k) Applicant

Broncus Medical, Inc.
1400 N. Shoreline Blvd, Suite A8
Mountain View, California 94043
Phone: (650) 428-1600
FAX: (650) 428-1542

Contact Person: Gary Kaplan
Phone: (650) 428-1600
Fax: (650) 428-1542
e-mail: gkaplan@broncus.com

3. Device Overview

Trade Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)

Common Name: Sheath and Dilation Balloon

Classification Name: Bronchoscope and Accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System (with FlexNeedle)	Broncus Technologies, Inc*	K112051, cleared to market on October 12, 2011 (and K093423, K091160 and K090095, by reference)
inReach System	SuperDimension	K110093, cleared to market on February 11, 2011 (and K071473, K092365 and K102604, by reference)
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002
*NOTE: Broncus Technologies, Inc changed their name to Broncus Medical, Inc in June 2012.		

5. Device Description

The LungPoint Tools are endoscopic tools used during bronchoscopy procedures. The LungPoint Sheath is designed to be used with a bronchoscope to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted lung tissue within the respiratory organs. It is advanced to a predefined target following guidance of the LungPoint Software. The LungPoint Dilation Balloon is used to dilate tissue of the bronchial tree and may be inserted through the sheath or directly through the working channel of the bronchoscope.

The materials used in the LungPoint Tools are commonly used medical grade materials and include platinum iridium markers.

The LungPoint Sheath has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

The LungPoint Dilation Balloon has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

6. Intended Use

The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

7. Comparison to Predicate Device

The LungPoint Tools are commonly used endoscopic tools with the same technological characteristics as the predicate devices. The indications for use of the LungPoint Tools for use with the LungPoint Software are all within the intended use of the predicate device, which is to enable treatment and diagnosis of lung cancer. The technological

characteristics of the subject devices are the same as those of the predicate devices with the exception of the balloon size and length, balloon burst pressure and balloon catheter length as outlined.

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	LungPoint Dilation Balloon
Balloon Size and Inflation (balloon pressure)	8mm @ 3 ATM 9mm @ 5.5 ATM 10mm @ 9 ATM	4mm @ 10 ATM
Catheter Length (cm)	155	143
Balloon Length (cm)	3.0	0.6
Rated Burst Pressure (atmospheres)	9	20

None of these differences raise new questions of safety and effectiveness. Performance of the subject devices has been verified by use of accepted methods.

8. Performance Data

The design and safety of the LungPoint Tools were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use. Testing included the following:

- Dimensional testing
- Joint/tensile test
- Simulated use
- Balloon fatigue/burst pressure
- Radiopacity.

All testing results met the pre-determined acceptance criteria that were established in the test protocols. Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

9. Safety and Effectiveness

The LungPoint Tools labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the devices. The biocompatibility assessment of all patient contacting materials was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices*. Specifically, cytotoxicity, sensitization, intracutaneous reactivity and systemic toxicity (acute) were tested. In addition, the devices are sterilized using e-beam sterilization.

10. Conclusion

Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

Attachment 3: FDA Form 3654 for ISO 15223

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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]

BS EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
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 descr bed; 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
BS EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative references, Terms and defintions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Symbols in the following Sections were applied: 5.1.1, 5.1.4, 5.1.5, 5.1.6, 5.1.7, 5.2.4, 5.4.2, 5.4.3

DESCRIPTION
Symbols were chosen from the sections above.

JUSTIFICATION
Not all symbols in the standard were applicable.

* 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.

Broncus Medical, Inc.
1400 N. Shoreline Blvd.
Suite A8
Mountain View, CA 94043
www.broncus.com

(650) 428-1600
(650) 428-1542 fax

April 22, 2013

Dear Ms. (b)(6)

In response to your email dated April 19, 2013, we are submitting the attached response to your questions. Your questions are identified in bold text. The corresponding Broncus responses are identified in normal text immediately following each question or part of a question.

The following attachments are included with the response,

Attachment 1: Updated Instructions for Use LungPoint Dilation Balloon
Attachment 2: Updated 510(k) Summary
Attachment 3: FDA Form 3654 for ISO 15223.

With the exception of the 510(k) summary, changes to the attached files, where appropriate, are underlined.

Please feel free to contact me should you have any additional questions.

Regards,

(b)(6)

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Attachment 1: Updated Instructions for Use LungPoint Dilation Balloon

Broncus Medical Inc.

LungPoint™ Dilation Balloon

REF **Catalog number 10008**

Instructions For Use (IFU)

Table of Contents

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or other endoscopic tool, such as a sheath, and is used to dilate lung tissue. The balloon may be used during interventional bronchoscopy procedures as determined by the physician performing the bronchoscopy.

The LungPoint Dilation Balloon is comprised of a catheter with a non-compliant 4mm OD x 6mm long inflatable balloon at the distal end and a y-connector with female luer fittings at the proximal end. The side port of the Y connector is used for inflation and deflation of the balloon with a standard indeflator capable of 12atm pressure (typically with a gage) and a male luer lock connector. The center port contains a nitinol wire which is fixed in place for pushability and kink resistance during tortuous bronchoscopic navigation. Included are two radiopaque marker bands and the distal and proximal ends of the balloon inflation length for visualization of the device position under fluoroscopy

Product Configuration and Dimensions

The LungPoint Dilation Balloon (see illustration in Figure 1) has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

2 Intended Use

The LungPoint Dilation Balloon is part of the LungPoint Tools, which are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

3 Contraindications

There are no known contraindications.

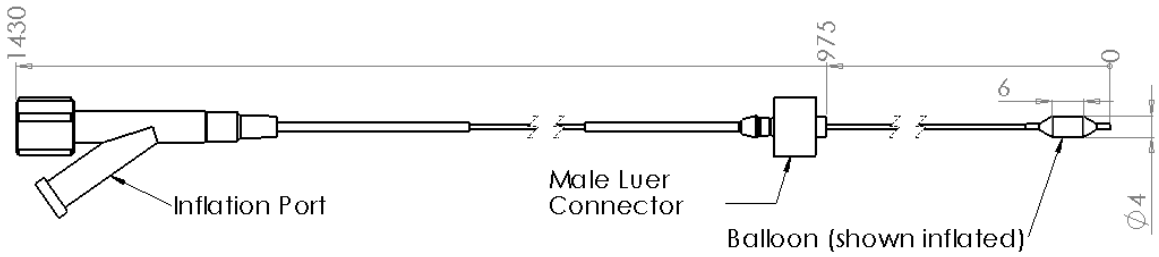


Figure 1: Dilation Balloon (shown inflated)

WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Dilation Balloon should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- The LungPoint Dilation Balloon should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Dilation Balloon in contradiction to the instructions may harm the device, bronchoscope or patient.
- The rated burst pressure is 20 atmosphere, exceeding the rated burst pressure may result in harm to the patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

6.1 Materials Required

- LungPoint Dilation Balloon
- Indeflator capable of 12atm
- Flexible bronchoscope with a working channel of 2.0 mm or greater

6.2 Device Inspection and Preparation

6.2.1 Read all IFUs, package inserts, labels, and warnings for the LungPoint Dilation Balloon before beginning the procedure.

CAUTION: Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.

6.2.2 Aseptically remove the LungPoint Dilation Balloon from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: If any damage or irregularity is found, **DO NOT USE** the device as this could result in harm to the patient.

CAUTION: DO NOT USE the device past its “Use Before” (expiration) date.

CAUTION: DO NOT place or manipulate the catheter in the airways unless under direct visualization with a bronchoscope or using fluoroscopy as this may result in harm to the patient.

7 Operating Instructions

7.1 Carefully advance the balloon through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 Connect the indeflator via the luer lock connector and inflate to 10atm. Do not exceed the rated burst pressure of 20 atm.

7.4 If using fluoroscopy – visualize balloon inflation location via the radiopaque marker bands and the distal and proximal ends of the balloon inflation length.

7.5 Deflate the balloon, and remove the device

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the device or bronchoscope.

7.6 At the completion of the patient procedure, dispose of the device in accordance with applicable hospital, local, state and federal laws and regulations.

NOTE: The LungPoint Dilation Balloon has been tested to three insertion cycles, meaning that the dilation balloon can be inserted/inflated/deflated/removed a total of three times and must be discarded after the third complete cycle.

8 Storage

Store at controlled room temperature.

Broncus Medical Inc.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Caution: consult instructions for use
	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
	Serial number or batch code
	Use before
	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Attachment 2: Updated 510(k) Summary

510(k) Summary

1. Date of Summary

April 22, 2013

2. 510(k) Applicant

Broncus Medical, Inc.
1400 N. Shoreline Blvd, Suite A8
Mountain View, California 94043
Phone: (650) 428-1600
FAX: (650) 428-1542

Contact Person: Gary Kaplan
Phone: (650) 428-1600
Fax: (650) 428-1542
e-mail: gkaplan@broncus.com

3. Device Overview

Trade Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)

Common Name: Sheath and Dilation Balloon

Classification Name: Bronchoscope and Accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System (with FlexNeedle)	Broncus Technologies, Inc*	K112051, cleared to market on October 12, 2011 (and K093423, K091160 and K090095, by reference)
inReach System	SuperDimension	K110093, cleared to market on February 11, 2011 (and K071473, K092365 and K102604, by reference)
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002
*NOTE: Broncus Technologies, Inc changed their name to Broncus Medical, Inc in June 2012.		

5. Device Description

The LungPoint Tools are endoscopic tools used during bronchoscopy procedures. The LungPoint Sheath is designed to be used with a bronchoscope to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted lung tissue within the respiratory organs. It is advanced to a predefined target following guidance of the LungPoint Software. The LungPoint Dilation Balloon is used to dilate tissue of the bronchial tree and may be inserted through the sheath or directly through the working channel of the bronchoscope.

The materials used in the LungPoint Tools are commonly used medical grade materials and include platinum iridium markers.

The LungPoint Sheath has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

The LungPoint Dilation Balloon has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

6. Intended Use

The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

7. Comparison to Predicate Device

The LungPoint Tools are commonly used endoscopic tools with the same technological characteristics as the predicate devices. The indications for use of the LungPoint Tools for use with the LungPoint Software are all within the intended use of the predicate device, which is to enable treatment and diagnosis of lung cancer. The technological

characteristics of the subject devices are the same as those of the predicate devices with the exception of the balloon size and length, balloon burst pressure and balloon catheter length as outlined.

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	**LungPoint Dilation Balloon**
Balloon Size and Inflation (balloon pressure)	8mm @ 3 ATM 9mm @ 5.5 ATM 10mm @ 9 ATM	4mm @ 10 ATM
Catheter Length (cm)	155	143
Balloon Length (cm)	3.0	0.6
Rated Burst Pressure (atmospheres)	9	20

None of these differences raise new questions of safety and effectiveness. Performance of the subject devices has been verified by use of accepted methods.

8. Performance Data

The design and safety of the LungPoint Tools were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use. Testing included the following:

- Dimensional testing
- Joint/tensile test
- Simulated use
- Balloon fatigue/burst pressure
- Radiopacity.

All testing results met the pre-determined acceptance criteria that were established in the test protocols. Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

9. Safety and Effectiveness

The LungPoint Tools labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the devices. The biocompatibility assessment of all patient contacting materials was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices*. Specifically, cytotoxicity, sensitization, intracutaneous reactivity and systemic toxicity (acute) were tested. In addition, the devices are sterilized using e-beam sterilization.

10. Conclusion

Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

Attachment 3: FDA Form 3654 for ISO 15223

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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]

BS EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
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 descr bed; 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.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
BS EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative references, Terms and defintions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Symbols in the following Sections were applied: 5.1.1, 5.1.4, 5.1.5, 5.1.6, 5.1.7, 5.2.4, 5.4.2, 5.4.3

DESCRIPTION
Symbols were chosen from the sections above.

JUSTIFICATION
Not all symbols in the standard were applicable.

* 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

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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.

K131234/S1

[redacted]

August 20, 2013

Dear Ms. (b)(6)

In response to your email dated June 12, 2013, we are submitting the attached response to the questions posed by FDA. FDA's questions are identified in bold text. The corresponding Broncus responses are identified in normal text immediately following each question.

The following attachments are included with the response,

Attachment 1: Updated Section 12 - Substantial Equivalence Discussion
Attachment 2: Updated 510(k) Summary
Attachment 3: Predicate Device Labeling - Olympus Guide Sheath
Attachment 4: Instructions for Use LungPoint Dilation Balloon
Attachment 5: Instructions for Use LungPoint Sheath
Attachment 6: (b)(4)
Attachment 7:
Data
Attachment 8:
Attachment 9:

This submission includes one original paper copy and one electronic copy. The electronic copy included here is an exact duplicate of the original paper submission.

Please feel free to contact me should you have any additional questions at (b)(4)

Regards,

(b)(6)

RA Consultant

24

Broncus Medical, Inc.
1400 N. Shoreline Blvd.
Suite A8
Mountain View, CA 94043
www.broncus.com

(650) 428-1600
(650) 428-1542 fax

August 20, 2013

Dear Ms (b)(6)

In response to your email dated June 12, 2013, we are submitting the attached response to the questions posed by FDA. FDA's questions are identified in bold text. The corresponding Broncus responses are identified in normal text immediately following each question.

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Attachment 1: Updated Section 12 - Substantial Equivalence Discussion
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Attachment 4: Instructions for Use LungPoint Dilation Balloon
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Attachment 6 (b)(4)
Attachment 7
Data
Attachment 8
Attachment 9

This submission includes one original paper copy and one electronic copy. The electronic copy included here is an exact duplicate of the original paper submission.

Please feel free to contact me should you have any additional questions at (b)(4)

Regards,

(b)(6)

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

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(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Attachment 1: Updated Section 12 - Substantial Equivalence Discussion

SECTION 12: SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1 Predicate Devices

The LungPoint Tools (LungPoint Dilation Balloon and LungPoint Sheath), which are designed to be used as accessories to the LungPoint Software System (cleared to market with a transbronchial aspiration needle on October 12, 2011 (K112051)), are commonly used endoscopic tools.

The predicate devices identified for the LungPoint Dilation Balloon and LungPoint Sheath are as follows:

Trade Name	510(k) Submitter	510(k) Number
Olympus Guide Sheath	Olympus Medical Systems Corporation	K060243, cleared to market on June 23, 2006
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002

12.2 Comparison to the Predicate Devices

The following tables outline the similarities and differences between the LungPoint Tools and the predicate devices.

Table 12.2.-1: Comparison Table - LungPoint Sheath

	Olympus Guide Sheath (K060243)	LungPoint Sheath
Indications for use	This instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasound probe to the target area within the respiratory organs.	The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.
(b)(4)	[redacted]	
Fluoro Tip/Radiopaque Markers	Yes	Yes
Delivery Approach	Visual (via bronchoscope) and/or Fluoroscopy	Visual (via bronchoscope) and/or Fluoroscopy
Delivered Through	Flexible bronchoscope with minimum working channel of (b) mm	Flexible bronchoscope with minimum working channel of (b) .mm
Single Use	Yes	Yes

Table 12.2-2: Comparison Table - LungPoint Dilation Balloon

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	LungPoint Dilation Balloon
Indications for use	The CRE Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.	The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.
(b)(4)	[redacted]	[redacted]
Tensile Strength	Complies with ISO 10555 as it is the industry standard	Complies with ISO 10555
Delivery Approach	Visual via bronchoscope	Visual via bronchoscope
Delivered Through	Flexible bronchoscope with minimum working channel of (b) mm	Flexible bronchoscope with minimum working channel of (b) .mm
Single Use	Yes	Yes
(b)(4)	[redacted]	[redacted]

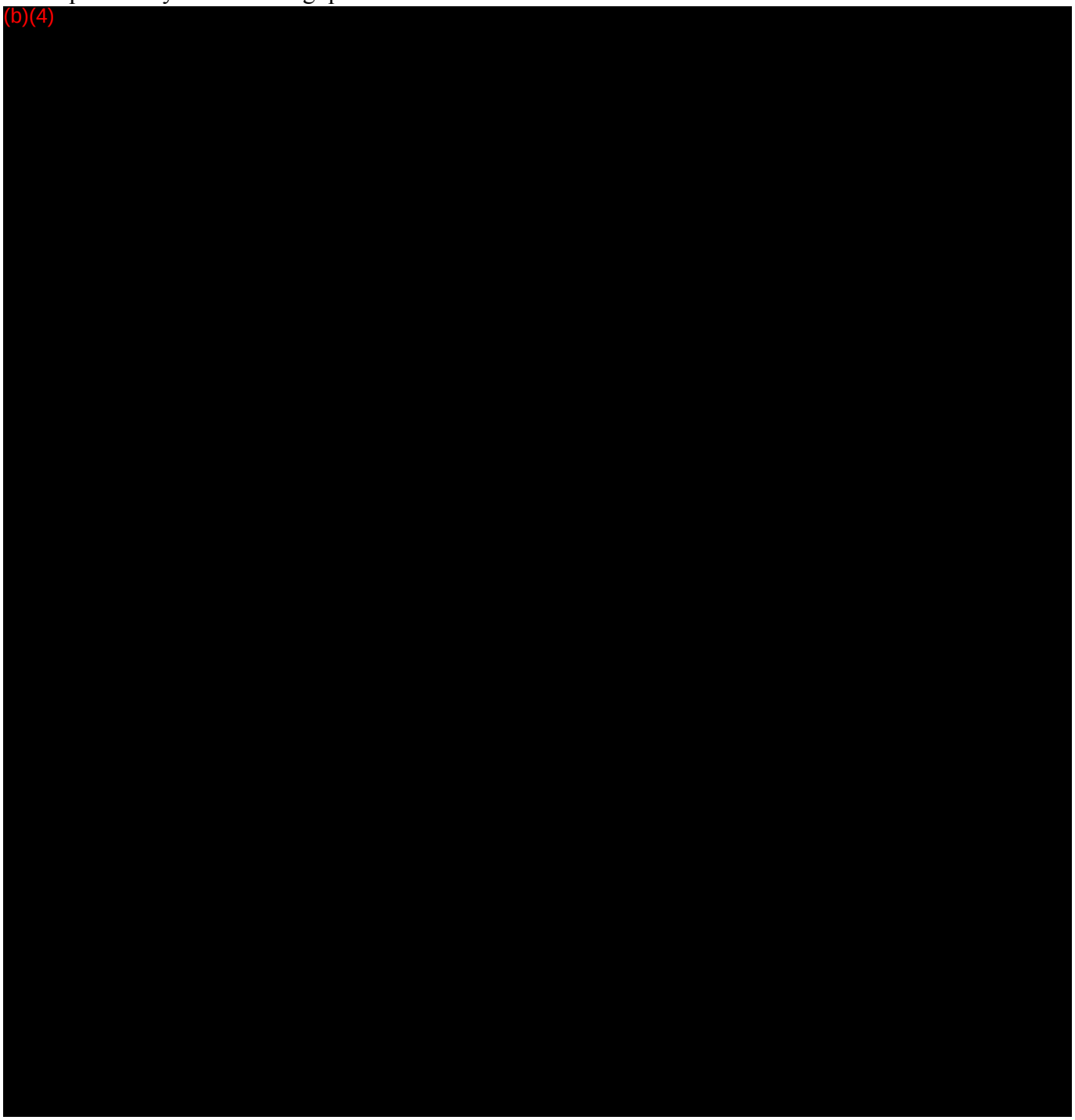
12.3 Substantial Equivalence Discussion

The LungPoint Tools (LungPoint Sheath and Dilation Balloon), the subject devices of this premarket notification, are substantially equivalent to the predicate devices. As outlined above, the LungPoint Tools have the same intended use and technological characteristics as their respective predicate devices.

In making this determination, Broncus followed the FDA's Draft Guidance entitled The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (December 27, 2011), the detailed flowchart provided in the guidance (included at the end of this section) and 21 CFR 807.100.

Specifically the following questions were considered:

(b)(4)



(b)(4) Deficiencies

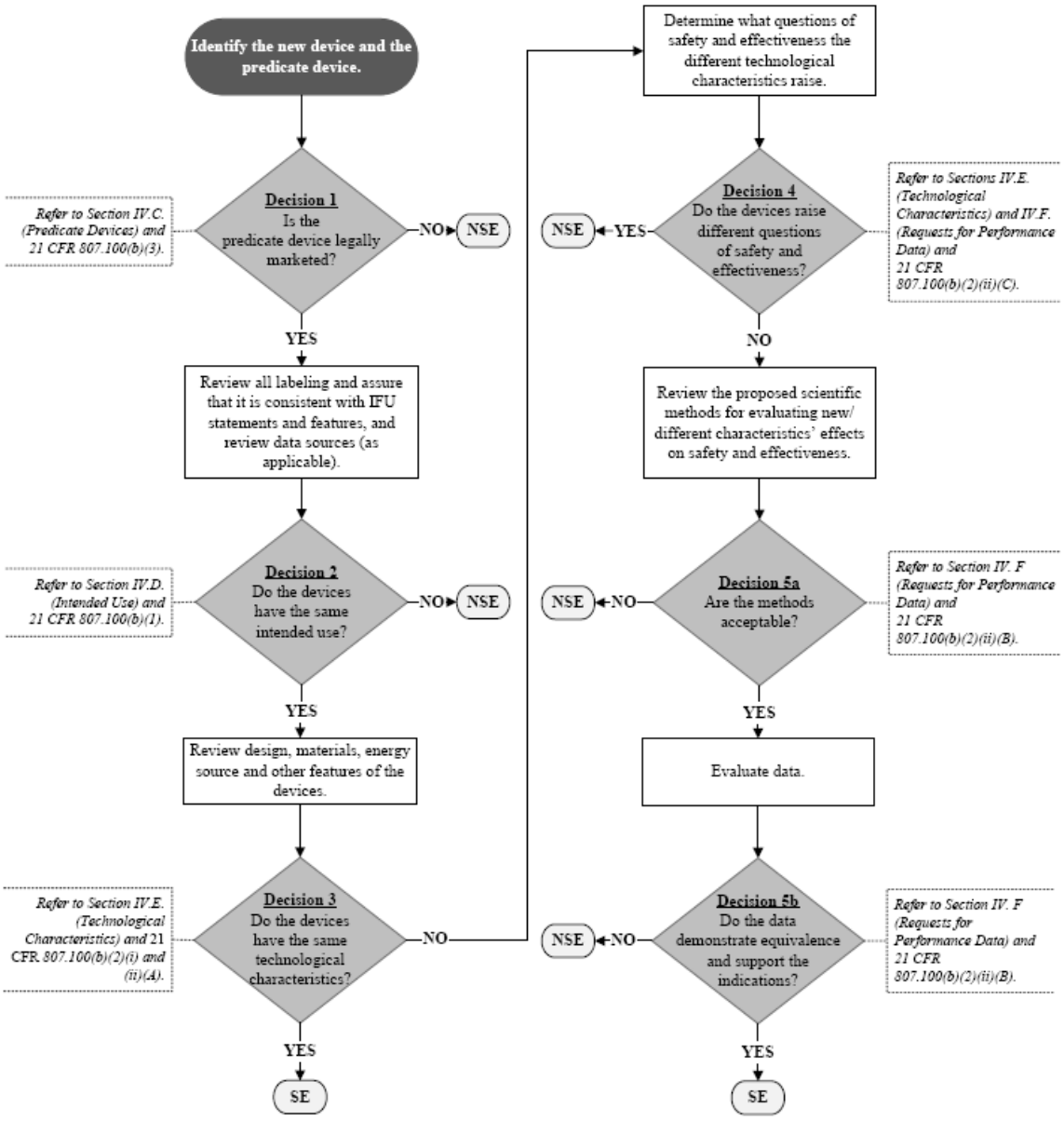
[redacted]

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]



SE = "Substantially Equivalent"
NSE = "Not Substantially Equivalent"

This Flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.

Figure 1: 510(k) "Substantial Equivalence" Decision-Making Flowchart

Attachment 2: Updated 510(k) Summary

510(k) Summary

1. Date of Summary

August 20, 2013

2. 510(k) Applicant

Broncus Medical, Inc.
1400 N. Shoreline Blvd, Suite A8
Mountain View, California 94043
Phone: (650) 428-1600
FAX: (650) 428-1542

Contact Person: Gary Kaplan
Phone: (650) 428-1600
Fax: (650) 428-1542
e-mail: gkaplan@broncus.com

3. Device Overview

Trade Name: LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon)

Common Name: Sheath and Dilation Balloon

Classification Name: Bronchoscope and Accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
CRE Pulmonary Balloon Dilatation Catheter	Boston Scientific Corporation	K023337, cleared to market on November 18, 2002
Olympus Guide Sheath	Olympus Medical Systems Corporation	K060243, cleared to market on June 23, 2006

5. Device Description

The LungPoint Tools are endoscopic tools used during bronchoscopy procedures. The LungPoint Sheath is designed to be used with a bronchoscope to provide a working

channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted lung tissue within the respiratory organs. The LungPoint Dilation Balloon is used to dilate tissue of the bronchial tree and may be inserted through the sheath or directly through the working channel of the bronchoscope. The bronchoscope is advanced to a predefined target following guidance of the LungPoint Software.

The materials used in the LungPoint Tools are commonly used medical grade materials and include platinum iridium markers.

The LungPoint Sheath has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

The LungPoint Dilation Balloon has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

6. Intended Use

The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

7. Comparison to Predicate Device

The LungPoint Tools are commonly used endoscopic tools with the same technological characteristics as the predicate devices. The indications for use of the LungPoint Tools for use with a bronchoscope guided by the LungPoint Software are all within the intended use of the predicate devices, which is to aid in reaching a target in the respiratory organ either directly as is the case with the sheath or through dilating target tissue with the dilation balloon. The technological characteristics of the subject devices are the same as those of the predicate devices with the following exceptions

- LungPoint Balloon: balloon size and length, balloon burst pressure and balloon catheter length as outlined.

	CRE Pulmonary Balloon Dilatation Catheter (K023337)	LungPoint Dilation Balloon
Balloon Size and Inflation (balloon pressure)	8mm @ 3 ATM 9mm @ 5.5 ATM 10mm @ 9 ATM	4mm @ 10 ATM
Catheter Length (cm)	155	143
Balloon Length (cm)	3.0	0.6
Rated Burst Pressure (atmospheres)	9	20

- LungPoint Sheath: stylet, catheter ID/OD and catheter length as outlined.

	Olympus Guide Sheath (K060243)	LungPoint Sheath
Stylet Provided	No	Yes - used to enhance pushability and to prevent airway mucosa entering sheath
Catheter ID/OD	2.1/2.7 mm	2.0/2.6 mm
Catheter Length	900 mm	975 mm

None of these differences raise new questions of safety and effectiveness. Performance of the subject devices has been verified by use of accepted methods.

8. Performance Data

The design and safety of the LungPoint Tools were verified by performing functional and performance testing. All tests were designed to subject the sheath and dilation balloon to stresses that exceed those which would be encountered during clinical use. Testing included the following:

- Dimensional testing
- Joint/tensile test
- Simulated use
- Balloon fatigue/burst pressure
- Balloon deflation time
- Radiopacity.

All testing results met the pre-determined acceptance criteria that were established in the test protocols. Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

9. Safety and Effectiveness

The LungPoint Tools labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the devices. The biocompatibility

assessment of all patient contacting materials was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices*. Specifically, cytotoxicity, sensitization, intracutaneous reactivity and systemic toxicity (acute) were tested. In addition, the devices are sterilized using e-beam sterilization.

10. Conclusion

Based on the testing the LungPoint Tools are as safe, as effective, and perform at least as safely and effectively as the predicate devices.

Attachment 3: Predicate Device Labeling - Olympus Guide Sheath

K060243

JUN 23 2006

January 23 , 2006

SMDA 510(k) SUMMARY
"Olympus Guide Sheath, XBO1-836-13 "

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. GENERAL INFORMATION

1. Applicant :

Olympus Medical Systems Corporation
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Registration number :8010047

2. Official Correspondent :

Laura Storm-Tyler
Executive Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-9058, USA
TEL 631-844-5688
FAX 631-844-5554
Registration Number :2429304

3. Manufacturer :

Aomori Olympus Co., Ltd.
2-248-1 Okkonoki Kuroishi-shi, Aomori-ken,
036-0357, Japan
Registration Number : 9614641

B. DEVICE IDENTIFICATION

1. Common/Usual Name : Bronchoscope accessory

2. Device Name : Olympus Guide Sheath, XBO1-836-13

3. Classification Name : 874.4680, class II , EOQ

C. PREDICATE DEVICES

Device Name	510(k) #	Manufacturer	Class	Product Code
Cytology Brush: BC-14/15/16C (EVIS 200 System)	#K931154	Olympus Corporation.	II	EOQ

1 of 2

83

D. SUMMARY DESCRIPTION OF THE DEVICE

1. Summary

Olympus Medical Systems Corp., intends to introduce the Guide Sheath for use in the respiratory organs. This Guide Sheath,XBO1-836-13 has been designed to be used with Olympus bronchoscopes with 2.8 mm instrument channel, accessories and ultrasonic probe unit for performing diagnostic and therapeutic procedures. The Guide Sheath allows physicians to advance the endo-therapy accessories or guide the ultrasonic probe precisely to the targeted lesions repeatedly.

2. Materials

The patient contacting materials used as components of the Guide Sheath are identical to legally Marketed Olympus products.

E. SUMMARY

In summary, the Guide Sheath, XBO1-836-13 is basically identical to the predicate device in performance, materials and specifications. The subject device differs from the predicate device relative to the intended use.

F. INTENDED USE OF THE DEVICE

This instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasound probe to the targeted area within the respiratory organs.

G. TECHNOLOGICAL CHARACTERISTICS

This Guide Sheath, XBO1-836-13 consists of tube sheath and piece of flouro tip, which shows the distal end position when X-ray was monitored. The following is the specification of the Guide Sheath;

Specifications	Dimension (m)
Outer Diameter	2.7
Inner Diameter	2.1
Sheath Length	900
Channel Size (Minimum ϕ)	2.8
Fluoro Tip for X-ray monitor	Provided

H. CLINICAL DATA

Olympus sponsored prospective clinical evaluation of the subject device which support the safe and effective use of the subject device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

Olympus Medical Systems Corporation
c/o Ms. Laura Storm-Tyler
Two Corporate Center Dr.
Melville, NY 11747-9058

Re: K060243
Trade/Device Name: Olympus Guide Sheath, XBO1-836-13
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and accessories (flexible or rigid)
Regulation Class: II
Product Code: EOQ
Dated: May 30, 2006
Received: May 31, 2006

Dear Ms. Storm-Tyler:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) : K060243

Device Name: Olympus Guide Sheath, XBO1-836-13

Indications for Use :

This instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasound probe to the target area within the respiratory organs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Karen A. Baker

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K060243

Attachment 4: Instructions for Use LungPoint Dilation Balloon

Broncus Medical Inc.

LungPoint™ Dilation Balloon

REF **Catalog number 10008**

Instructions For Use (IFU)

Table of Contents

Broncus Medical Inc.

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Dilation Balloon is an endoscopic tool that is used to dilate the target lung tissue of the bronchial tree. The dilation balloon is inserted through the bronchoscope or other endoscopic tool, such as a sheath, and is used to dilate lung tissue. The balloon may be used during interventional bronchoscopy procedures as determined by the physician performing the bronchoscopy.

The LungPoint Dilation Balloon is comprised of a catheter with a non-compliant 4mm OD x 6mm long inflatable balloon at the distal end and a y-connector with female luer fittings at the proximal end. The side port of the Y connector is used for inflation and deflation of the balloon with a standard indeflator capable of 12atm pressure (typically with a gage) and a male luer lock connector. The center port contains a nitinol wire which is fixed in place for pushability and kink resistance during tortuous bronchoscopic navigation. Included are two radiopaque marker bands and the distal and proximal ends of the balloon inflation length for visualization of the device position under fluoroscopy

Product Configuration and Dimensions

The LungPoint Dilation Balloon (see illustration in Figure 1) has the following specifications:

Catalog Number	Balloon Size (OD x length)	Rated Balloon Pressure	Maximum Catheter Outer Diameter (OD)	Catheter Length/working length
10008-1	4mm x 6mm	20atm	1mm	1430mm/975mm

Additionally, the LungPoint Dilation Balloon should be used with a flexible bronchoscope with a working channel of 2.0 mm or greater.

2 Intended Use

The LungPoint Dilation Balloon is part of the LungPoint Tools, which are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

3 Contraindications

There are no known contraindications.

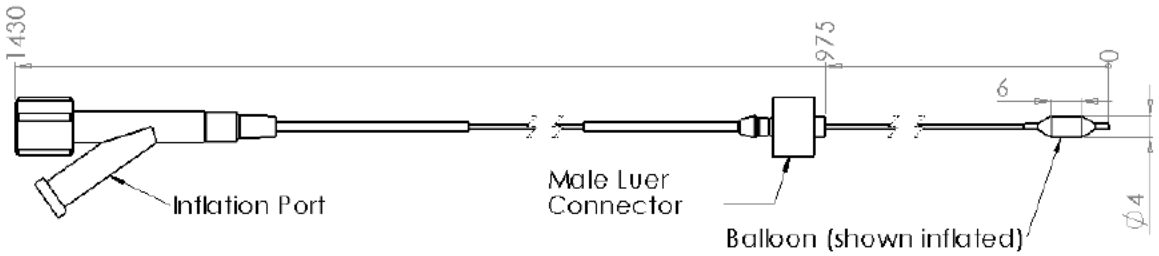


Figure 1: Dilation Balloon (shown inflated)

⚠ WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Dilation Balloon should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- The LungPoint Dilation Balloon should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Dilation Balloon in contradiction to the instructions may harm the device, bronchoscope or patient.
- The rated burst pressure is 20 atmosphere, exceeding the rated burst pressure may result in harm to the patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

6.1 Materials Required

- LungPoint Dilation Balloon
- Indeflator capable of 12atm
- Flexible bronchoscope with a working channel of 2.0 mm or greater

6.2 Device Inspection and Preparation

6.2.1 Read all IFUs, package inserts, labels, and warnings for the LungPoint Dilation Balloon before beginning the procedure.

CAUTION: Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.

6.2.2 Aseptically remove the LungPoint Dilation Balloon from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: If any damage or irregularity is found, **DO NOT USE** the device as this could result in harm to the patient.

CAUTION: DO NOT USE the device past its “Use Before” (expiration) date.

CAUTION: DO NOT place or manipulate the catheter in the airways unless under direct visualization with a bronchoscope or using fluoroscopy as this may result in harm to the patient.

7 Operating Instructions

7.1 Carefully advance the balloon through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 Connect the indeflator via the luer lock connector and inflate to 10atm. Do not exceed the rated burst pressure of 20 atm.

7.4 If using fluoroscopy – visualize balloon inflation location via the radiopaque marker bands and the distal and proximal ends of the balloon inflation length.

7.5 Deflate the balloon, and remove the device

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the device or bronchoscope.

7.6 At the completion of the patient procedure, dispose of the device in accordance with applicable hospital, local, state and federal laws and regulations.

8 Storage

Store at controlled room temperature.

Broncus Medical Inc.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Caution: consult instructions for use
	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
	Serial number or batch code
	Use before
	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Attachment 5: Instructions for Use LungPoint Sheath

Broncus Medical Inc.

LungPoint™ Sheath

REF **Catalog number 10007**

Instructions For Use (IFU)

Table of Contents

Broncus Medical Inc.

Rx only	**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.
STERILE R	Contents are supplied irradiation sterilized.
2	For single-patient-use only. Do not re-use or re-sterilize.

1 Device Description

The LungPoint Sheath is an endoscopic tool that is designed to be used with bronchoscopes to provide a working channel through which endoscopic tools, such as needles, dilation balloons, or other endoscopic devices may be introduced to the targeted area within the respiratory organs.

The sheath enables physicians to easily access targets and allows for multiple approaches to the preselected target. It allows for the repeated placement of endoscopic tools to a specified lesion(s) during one procedure. The sheath is provided with a stylet, which is used to minimize the amount of airway mucosa entering the sheath's lumen and/or to provide rigidity (i.e. pushability).

The sheath (with stylet, if necessary) is inserted through a standard bronchoscope. It is then advanced to a target under the guidance of the LungPoint Software. Placement of the sheath may require the use of other endoscopic tools. Once placed, other endoscopic tools, such as needles, dilation balloons, or other endoscopic devices, may be introduced through the sheath to the targeted area within the respiratory organs. If a stylet is used, it must be removed prior to the introduction of the other tools.

The LungPoint Sheath is comprised of a braid reinforced tubing,to resist kinking with articulation along with an incorporated stylet. The stylet when mated, provides for a rounded tip during insertion and pushability for navigation to the target. Removal of the stylet allows for standard 2.0mm working channel bronchoscopic accessories to be used though the lumen of the sheath. The tip of the Sheath is marked visually with black bands at the tip and in 10mm increments to 60mm to provide the user with an indication of the traveled depth during insertion. Also included are multiple radiopaque marker bands at the distal end at the tip, 5mm, 10mm and 20mm to aid visualization of the sheath under fluoroscopy.

Product Configuration and Dimensions

The LungPoint Sheath (see illustration in Figure 1) has the following specifications:

Catalog Number	Working Length	Maximum Catheter Outer Diameter (OD)	Catheter Internal Diameter (ID)	Minimum accessory length for use through sheath
10007-1	900mm	2.65mm	2.0mm	965mm

Additionally, the LungPoint Sheath should be used with a flexible bronchoscope with a working channel of 2.8 mm or greater.

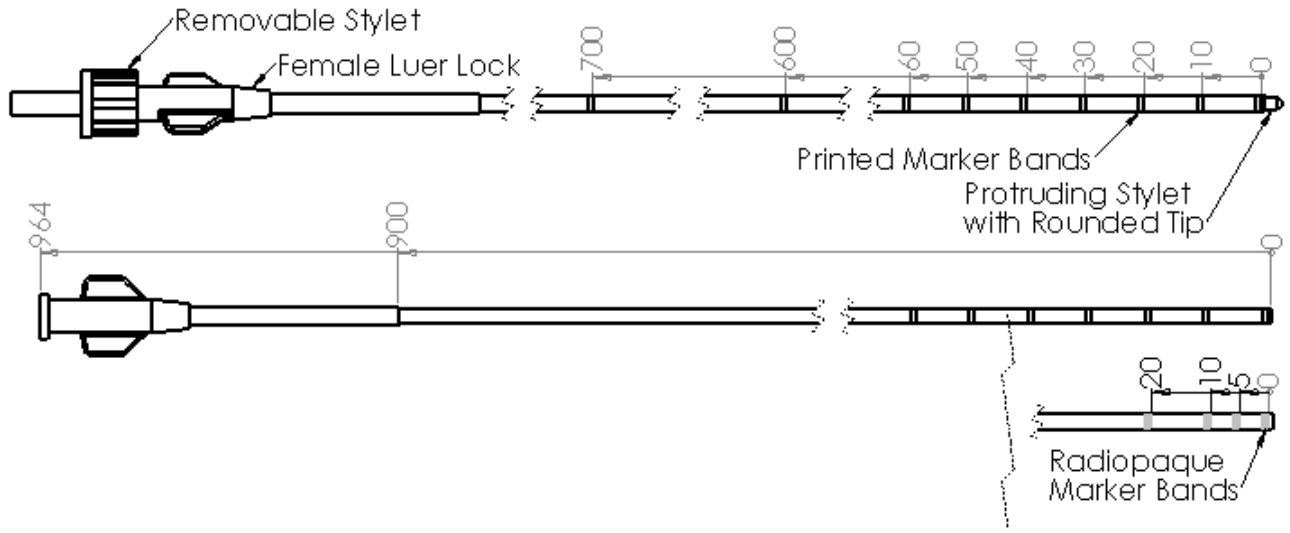


Figure 1: LungPoint Sheath

2 Intended Use

The LungPoint Sheath is part of the LungPoint Tools, which are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs in a minimally invasive manner.

3 Contraindications

There are no known contraindications.

WARNINGS AND PRECAUTIONS

4 Warnings / Precautions

- The LungPoint Sheath should only be used by physicians thoroughly trained in bronchoscopy and in the particular technique and procedure to be performed, and familiar with the associated risks. These operating instructions must be read, understood, and followed.
- DO NOT activate active devices (e.g., electrosurgical devices) inside the lumen of the sheath. The active portion of the device must be extended beyond the sheath prior to activation.
- While advancing the sheath, DO NOT USE excessive force as this may advance the device in an uncontrolled manner that could result in harm to the patient's airway wall and cause bleeding.
- The LungPoint Sheath should only be used in a manner consistent with the Bronchoscope manufacturer's Instructions for Use. Use of the LungPoint Sheath in contradiction to the instructions may harm the device, bronchoscope or patient.

5 Possible Complications

- Bleeding
- Infection

6 Preparation for Use

6.1 Materials Required

- LungPoint Sheath
- Luer-lock aspiration syringe
- Flexible bronchoscope with a working channel of 2.8 mm or greater

6.2 Device Inspection and Preparation

6.2.1 Read all IFUs, package inserts, labels, and warnings for the device before beginning the procedure.

CAUTION: **Inspect the sealed sterile device package before opening. If the seal is broken, contents may not be sterile and could pose a risk of patient infection.**

6.2.2 Aseptically remove the LungPoint Sheath from the package and inspect for any damage, such as broken or crushed areas of the catheter shaft, sharp or protruding edges at the distal tip, or any kinks in the catheter shaft.

CAUTION: **If any damage or irregularity is found,** DO NOT USE **the device as this could result in harm to the patient.**

CAUTION: DO NOT USE **the device past its "Use Before" (expiration) date.**

6.2.3 Before inserting the device into the working channel of the bronchoscope, verify that the stylet is secured to the sheath via the luer lock connection.

7 Operating Instructions

7.1 Carefully advance the Sheath through the working channel of the bronchoscope using short (approximately 20 mm) increments, until the distal end of the catheter is within bronchoscopic view.

CAUTION: DO NOT force the catheter if resistance to insertion is encountered. Reduce the angulation of the bronchoscope until the device passes smoothly. This can result in (a) kinks to the device, (b) damage to the bronchoscope, or (c) harm to the patient such as punctures, hemorrhage or mucous membrane damage.

CAUTION: If any damage occurs, including a kink, **DO NOT USE** and discard**.**

7.2 Advance the catheter to the desired protrusion from the bronchoscope as required for navigation to the region of interest.

CAUTION: Do not angulate the bronchoscope abruptly while the device is extended from the distal end of the bronchoscope. This can result in kinks to the device or harm to the patient such as punctures, hemorrhage or mucous membrane damage.

7.3 For accessory use: remove the stylet by loosening the luer lock connection and withdraw the stylet. Insert the accessory device into the lumen.

CAUTION: If excessive resistance makes withdrawal difficult, reduce the angulation of the bronchoscope until the accessory can be withdrawn smoothly. Forcible withdrawal could damage the sheath, accessory or bronchoscope.

7.4 If using fluoroscopy – visualize radiopaque accessory devices position relative to the tip marker band.

7.5 Withdraw the Sheath from the bronchoscope.

7.6 At the completion of the patient procedure, dispose of the device in accordance with applicable hospital, local, state and federal laws and regulations.

8 Storage

Store at controlled room temperature.

Broncus Medical Inc.

LEGAL NOTICE

Graphic Symbol Legend for Medical Device Labeling

REF	Catalog number
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Caution: consult instructions for use
	Irradiation sterilized. Sterility guaranteed if package unopened and undamaged.
	Serial number or batch code
	Use before
	For single use
	Manufacturer

Broncus Medical Inc.

Manufacturer:
Broncus Medical, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, CA, 94043 USA
(877) 428-1600

Attachment 6: Literature Reference

Dimensions of the Normal Human Trachea

Éamann Breatnach[1]
Gypsy C. Abbott[2]
Robert G. Fraser[1]

The coronal and sagittal diameters of the tracheal air column were measured on posteroanterior and lateral chest radiographs of 808 patients with no clinical or radiographic evidence of respiratory disease. The 430 male and 378 female subjects were 10–79 years of age. Assuming a normative range that encompasses three standard deviations from the mean or 99.7% of the normal population, the upper limits of normal for coronal and sagittal diameters, respectively, in men aged 20–79, are 25 mm and 27 mm; in women, they are 21 mm and 23 mm, respectively. The lower limit of normal for both dimensions is 13 mm in men and 10 mm in women. Deviation from these figures reflects pathologic widening or narrowing of the tracheal air column. No statistically significant correlation was found between tracheal caliber and body weight or body height.

Changes in tracheal dimensions occur in a variety of conditions. For example, generalized widening is a characteristic feature of tracheobronchomegaly and tracheomalacia; generalized narrowing is seen in tracheobronchopathia osteochondroplastica and may be a feature of relapsing polychondritis. Knowledge of normal tracheal dimensions on conventional chest radiographs is essential to the diagnosis of these conditions. Previously published figures for normal tracheal caliber show considerable variation and generally are based on sample populations of insufficient size to establish statistical validity for all decades. We measured the coronal and sagittal tracheal diameters on posteroanterior and lateral chest radiographs of a large sample of patients with no known respiratory disease to establish normal ranges for these measurements in men and women of various ages and to determine whether correlation exists between tracheal width and body weight or body height.

Subjects and Methods

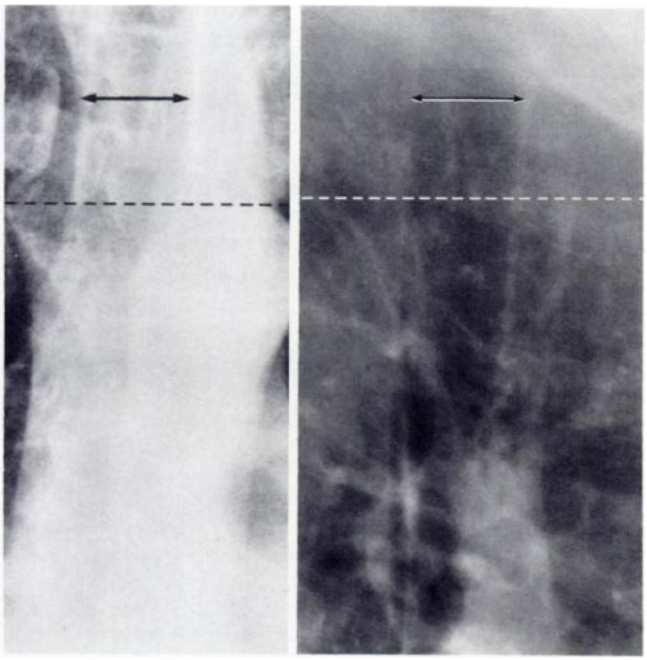
The chest radiographs of 808 patients (430 males and 378 females) were examined. Radiographs were obtained on maximal inspiration in posteroanterior and lateral projections using a focus-film distance of 10 feet (3.05 m) and a 6-inch (15.2 cm) air gap for scatter reduction. This technique results in a mid-plane magnification factor of 1.08, slightly less than the magnification factor of 1.10 obtained with the more conventional 6-foot (1.83 m) focus-film distance and grid technique. Exposures were made at 145 kVp and 500 mA for the posteroanterior projection and at 110 kVp and 700 mA for the lateral projection. All patients were ambulatory and had neither historical nor radiographic evidence of respiratory disease. Patients were included in the study only when their chest radiographs on maximal inspiration were technically adequate for accurate measurement of the intrathoracic trachea in both projections, and in whom local or general tracheal deformity from any cause was absent. Patients' age, height, and weight were recorded under supervision at the time of the radiographic examination. The internal diameter of the tracheal air column was measured at a level 2 cm above the projected top of the aortic arch on both posteroanterior and lateral radiographs to obtain coronal and sagittal dimensions, respectively (fig. 1). Measurements

Received July 6, 1983; accepted after revision December 14, 1983.

[1] Department of Diagnostic Radiology, University of Alabama, Birmingham Medical Center, 619 S. 19th St., Birmingham, AL 35233. Address reprint requests to E. Breatnach.

[2] Department of Statistics, University of Alabama, Birmingham Medical Center, Birmingham, AL 35233.

AJR 141:903–906, May 1984
0361–803X/84/1425–0903



A B

Fig. 1.—Level of measurement (*solid line*) of coronal (**A**) and sagittal (**B**) tracheal diameters, 2 cm above projected top of aortic arch (*broken line*).

were made of the air column alone, excluding the tracheal wall. This level was chosen because of the high visibility of the aortic arch on diagnostic chest radiographs, whereas the carina is not always precisely identifiable. Internal tracheal diameters were used for all measurements.

Results

Tracheal dimensions were grouped according to the subjects' age and gender, and the mean coronal and sagittal diameters (±SD) were calculated for each decade for males and females (table 1). In men, at all ages from 20 to 79 years, statistically significant differences ($p = 0.05$) were observed between sagittal and coronal diameters, the former being consistently greater than the latter (figs. 2 and 3). In women, although mean sagittal diameters were greater than coronal from the third decade on, the difference was not as great as in men and assumed statistical significance ($p = 0.05$) only in subjects over 49 years of age. In the third through eighth decades of life, the coronal and sagittal dimensions were greater in men than in women; the differences were statistically significant ($p = 0.05$). During the second decade, although the mean values in both dimensions were greater in boys than in girls, the differences between the genders were not statistically significant (fig. 4). Gender differences were observed in growth patterns (figs. 2 and 3): In men, both dimensions increased rather sharply during the second and third decades, then more slowly (but significantly) during the fourth decade; in women, growth was much more gradual from the second through fourth decades. In neither gender did any change occur in either dimension from the fourth decade on.

Relations between tracheal measurements and body weight and height were analyzed by multiple regression techniques, including cross-validation; no statistically significant correlation was found.

Discussion

The most commonly quoted figures for tracheal caliber in normal subjects are those of Katz et al. [1], Jesseph and Merendino [2], Greene [3], and Fraser and Paré [4]; data from these four studies are summarized in table 2. Although values for normal ranges are quoted elsewhere [5, 6], the data on which the figures are based generally lack statistical validity. It can be seen from table 2 that there is considerable variation in the normal ranges published. Greene [3] measured the internal tracheal diameter 1 cm above the aortic arch, whereas Jesseph and Merendino [2] used a point just proximal to the tracheal bifurcation. We found a point 2 cm above the aortic arch to be more consistently reproducible, though we observed no real variation between measurements taken at either level. The reported differences in normal ranges probably reflect, at least in part, differences in age groups and gender predominance among the populations studied. In the present study, we used a larger group of patients with convincing numeric representation for both genders in each decade from 10 to 79 years of age. The small size of the SD for each mean in our series indicates satisfactory numeric representation for each decade on a statistical basis and the validity of comparative data between the genders. The increase in coronal and sagittal tracheal dimensions for both genders up to age 30 (fig. 4) is important in assessing normal values for younger patients. The similarity between coronal and sagittal diameters in the second decade in males and in the second and third decades in females correlates well with the work of Engle [7], who found that the trachea in children and young adults is roughly circular in cross section. In all decades after ages 20 (men) and 30 (women), the trachea assumes a more ovoid shape in cross section; the differences betwen coronal and sagittal diameters are greater in men than in women.

Changes in tracheal dimensions occur in a variety of conditions; for example, there is dilatation in tracheobronchomegaly [1, 8] (fig. 5) and tracheomalacia [9] and narrowing in tracheobronchopathia osteochondroplastica [10], relapsing polychondritis [11], fibrosing mediastinitis [12, 13], rhinoscleroma [14], and "saber sheath" trachea [15]. The last-named deserves brief description.

Saber-sheath trachea, as defined by Greene and Lechner [15], involves a coronal tracheal diameter less than two-thirds the sagittal diameter (fig. 6). In Greene's later report [3], the mean coronal and sagittal diameters in a control group (60 men; mean age, 66.4 years) were 19.7 and 22.5 mm, respectively, and in a study group (60 men; mean age, 63.9 years) 12.0 and 25.8 mm, respectively. Such a pronounced difference between the two diameters was not seen in any of our patients, indicating that saber-sheath trachea is not a natural consequence of aging, as was suggested by Simmonds [16], cited by Greene [3]. That the deformity does not occur in the normal population at any age adds support to Greene's

TABLE 1: **Mean Coronal and Sagittal Tracheal Diameters in Normal Subjects by Gender and Age**

Age Group (years)	Male			Female		
	No. of Subjects	Tracheal Diameter (mm): Mean ± SD		No. of Subjects	Tracheal Diameter (mm): Mean ± SD	
		Coronal	Sagittal		Coronal	Sagittal
10–19	26	15.5 ± 2.8	15.4 ± 3:1	22	14.4 ± 1.6	14.5 ± 1.3
20–29	81	18.7 ± 2.0	19.3 ± 2.0	98	15.7 ± 1.6	15.6 ± 1.7
30–39	72	19.2 ± 2.1	19.7 ± 2.4	64	16.0 ± 1.8	16.3 ± 2.3
40–49	69	19.5 ± 2.3	20.3 ± 2.2	45	16.6 ± 2.0	16.8 ± 2.2
50–59	80	19.2 ± 2.3	20.4 ± 2.6	65	16.5 ± 1.6	17.0 ± 2.0
60–69	71	19.5 ± 2.2	20.7 ± 2.5	48	16.8 ± 2.0	17.2 ± 2.3
70–79	31	19.7 ± 2.2	20.8 ± 1.8	36	16.4 ± 2.4	16.5 ± 2.3

Note.—Coronal and sagittal tracheal diameters were defined as the internal diameters of the tracheal air column as measured at a level 2 cm above the projected top of the aortic arch on posteroanterior and lateral radiographs, respectively.

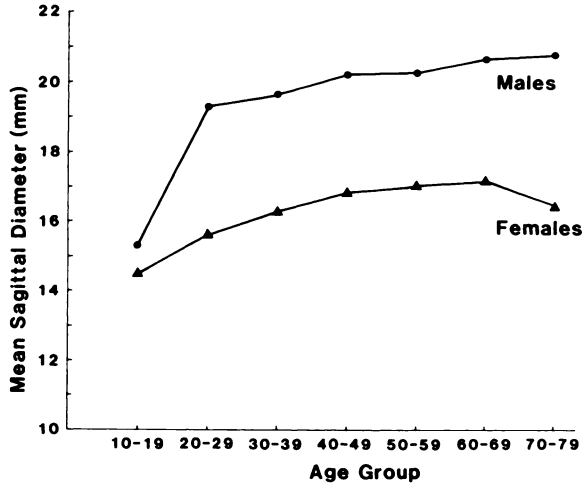


Fig. 2.—Mean sagittal tracheal diameters (mm) in normal subjects by gender and age group (decades).

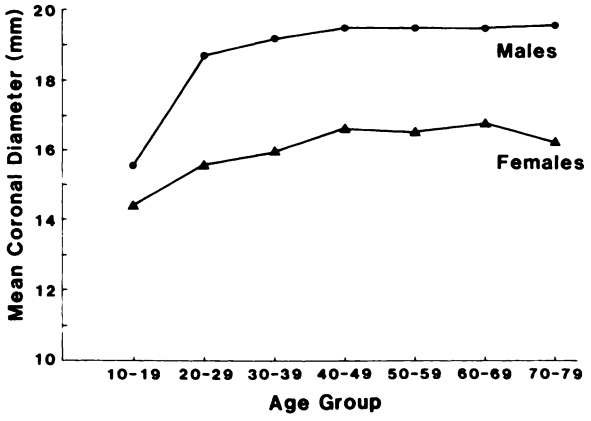


Fig. 3.—Mean coronal tracheal diameters (mm) in normal subjects by gender and age group (decades).

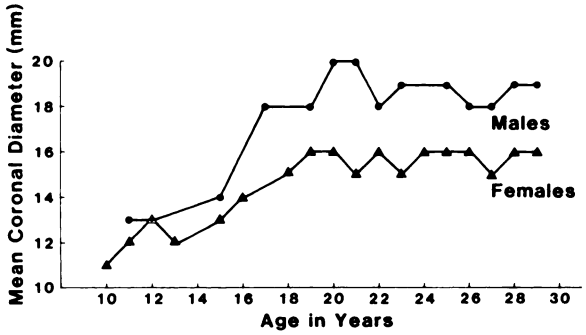


Fig. 4.—Mean coronal tracheal diameters (mm) in normal subjects by gender and age (years) during second decade of life.

contention [15] that it is almost invariably associated with chronic obstructive airway disease: Of the 60 patients with saber-sheath trachea, 95% had clinical evidence of chronic obstructive pulmonary disease, as compared with only 18% in the control group. The value of this radiographic sign is twofold: It indicates the presence of chronic obstructive pulmonary disease when other convincing radiographic evidence is lacking, and it militates against the erroneous assumption that coronal narrowing is caused by a mediastinal mass.

In our study, no correlation was observed between tracheal dimensions and subjects' weight or height. This contrasts with the results reported by Fraser and Paré [4] in a study of 350 chest radiographs of roughly equal numbers of asymptomatic men and women 30–80 years of age; these authors found that sagittal tracheal diameters increased gradually with increasing height, although neither age nor weight had any apparent influence. The average sagittal diameter increased from 17.6 mm in subjects 50–59 inches (127–150 cm) tall to 22.5 mm in subjects 70–72 inches (178–183 cm) tall; corresponding coronal dimensions were not recorded. We have no explanation for the discrepancy between the two studies regarding the effect of subjects' height on tracheal dimensions.

Assuming a normative range that encompasses three SDs from the mean, the upper limits of normal for coronal and sagittal diameters of the tracheal air column in men aged 20–79 are 25 and 27 mm, respectively; in women aged 20–79, they are 21 and 23 mm, respectively. The lower limit of normal for both dimensions is 13 mm in men and 10 mm in women. Any deviation from these figures indicates pathologic widening or narrowing of the tracheal air column.

ACKNOWLEDGMENT

We thank Sharon Compton for assistance with computer analysis.

TABLE 2: **Normal Coronal and Sagittal Tracheal Diameters Reported by Previous Investigators**

Reference	No. of Subjects (gender)	Age Range (mean) in Years	Tracheal Diameter (mm): Range (mean ± SD)	
			Coronal	Sagittal
[1]	50	...	13–25 (20.2 ± 3.4)	...
[2]	21 (M)	13–86	15–27 (22.0 ± 2.6)	...
	26 (F)		13–25 (17.0 ± 2.2)	...
[3]	60 (M)	(66.4)	15–26 (19.7 ± 2.0)	18–32 (22.5 ± 2.4)
[4]	175 (M)	30–80	11–26 (19.5)	11–30 (17.5)
	175 (F)		9–24 (15.5)	7–26 (15.5)

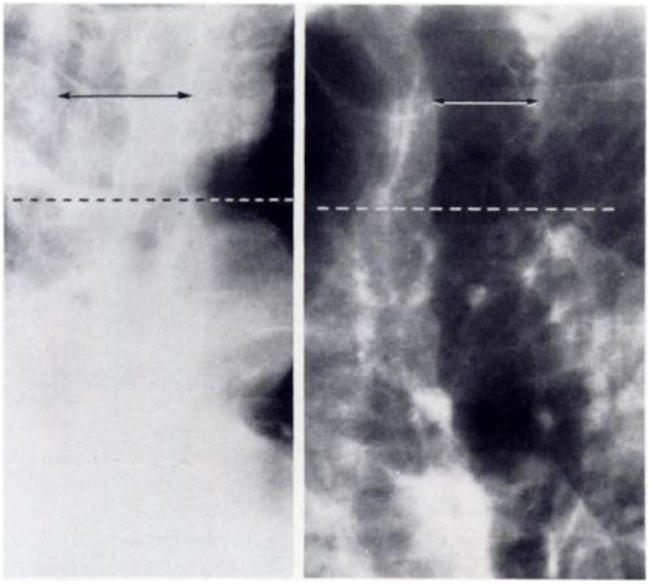


Fig. 5.—Tracheobronchomegaly (Mounier-Kuhn syndrome). Coronal diameter (**A,** *solid line*) = 31 mm; sagittal diameter (**B,** *solid line*) = 22 mm. (*Broken line* marks level of top of aortic arch.)

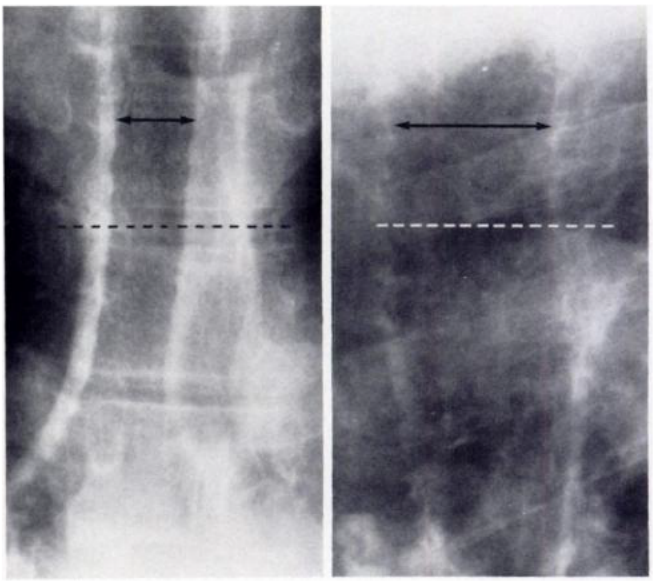


Fig. 6.—Saber-sheath trachea. Coronal diameter (**A,** *solid line*) = 16 mm; sagittal diameter (**B,** *solid line*) = 30 mm. (*Broken line* marks level of top of aortic arch.)

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Attachment 7: LungPoint Balloon, Simulated Use Testing including Deflation Time Test Data

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

Attachment 8: Dilation Balloon Drawings (Revision A and B)

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

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(b)(4) Schematic Drawings

Attachment 9: LungPoint Tools Shelf-life Report

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FDA Cover Letter

K131234

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FDA CDRH DMC

AUG 27 2013

Received

Date: August 26, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification 510(k) Electronic Copy:

K131234
Broncus Medical, Inc.
LungPoint Tools

To Whom It May Concern:

The electronic files (eCopy) are an exact duplicate of the paper copy included with this submission.

If you should have any questions regarding this submission please contact me at (b)(4) or fax (b)(4) or email (b)(4)
Please fax any correspondence regarding this submission to (b)(4)
(b)(4)

Sincerely,

(b)(6)

Responsible Third Party Official

(b)(4)

(b)(4)

(b)(4)

Revisi ffective

Date: August 26, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Additional Information for

K131234
Broncus Medical, Inc.
LungPoint Tools

To Whom It May Concern:

Enclosed in duplicate is the additional information received from Broncus Medical regarding K131234. This information has been reviewed in detail (see attached) review addendum and was found to answer the questions raised from a letter dated June 12, 2013 from Srinivas "Nandu" Nandkumar, Ph.D..

Recommendation: Substantial Equivalence

If you should have any further questions regarding this submission please contact me at (b)(4) or fax (b)(4) or email at (b)(4). Please fax any correspondence regarding this submission to (b)(4) (b)(4)

Sincerely

(b)(6)

Responsible Third Party Official

(b)(4) Deficiencies

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