DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

June 25, 2015

Bryan Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K150951
Trade/Device Name: Aeris 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: June 9, 2015
Received: June 10, 2015

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

Sincerely yours,

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 Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

Device Name
aeris Balloon Dilation Catheter

Indications for Use *(Describe)*
The aeris Balloon Dilation Catheter is intended for use in adult and pediatric populations to dilate strictures of the airway.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Bryan Medical, aeris Balloon Dilation Catheter

The assigned 510(k) number is: K150951

510(k) Owner: Andrew Georgilis
Bryan Medical, Inc.
3906 Oak St.
Cincinnati, OH 45227
Phone: (513) 272-1600
Fax: (513) 272-1610

Contact Person: Andy Black
Medical Murray, Inc.
400 North Rand Road
North Barrington, IL 60010
Phone: (847) 620-7990
Fax: (847) 620-7995

Date Prepared: January 30, 2015

Device Name and Classification

Classification Name: Bronchoscope (Flexible or Rigid) and Accessories

Common Name: Balloon Dilation Catheter

Name: aeris Balloon Dilation Catheter

Device Classification: Class II

Number: 21 CFR Ref. § 874.4680

Product Code: KTI

Review Panel: Ear, Nose, & Throat

Predicate Device: Acclarent Inspira AIR Balloon Dilation System (K090660)

Boston Scientific CRE Pulmonary Balloon Dilation Catheter (K023337)

Device Description

The aeris Balloon Dilation Catheter is comprised of a single lumen catheter with a high pressure balloon near the distal tip. A stylet is provided to facilitate advancement of the balloon dilation catheter to the desired location. The stylet must be removed before inflation of the high pressure balloon. A luer lock at the proximal end is used for placement of the stylet and injecting sterile water into the balloon. Two radiopaque markers, located on the catheter, inside the balloon, can be used to confirm balloon placement under Fluoroscopy.

The aeris Balloon Dilation Catheter includes inflation balloons of diameters 5, 7, 8, 9, 10, 12, 14, and 16 mm with complementing characteristics as shown in Table 1.

aeris Balloon Dilation Catheter Size	Product Number	Balloon Ø (mm)	Balloon Working Length (mm)	Recommended Use Pressure (ATM)	Catheter OD (mm)	Catheter Length (cm)
5 x 30 mm	KG0530	5	30	17	1.55	55
7 x 30 mm	KG0730	7	30	17	1.55	55
8 x 30 mm	KG0830	8	30	17	1.55	55
9 x 30 mm	KG0930	9	30	17	1.55	55
10 x 30 mm	KG1030	10	30	17	2.34	55
12 x 40 mm	KG1240	12	40	10	2.34	55
14 x 40 mm	KG1440	14	40	10	2.34	55
16 x 40 mm	KG1640	16	40	10	2.34	55

Table 1: aeris Balloon Dilation Catheter sizes and corresponding characteristics.

The aeris Balloon Dilation Catheter is provided in sterile packaging and with a protective sheath covering the balloon. After removing the catheter from the packaging and protective sheath, it is wiped down with a gauze pad soaked in sterile water. The catheter should then be gently advanced into the airway, to the site of the stricture under endoscopic visualization. The balloon portion of the device is then centered across the restriction and the stylet is removed while holding the catheter securely in place. The balloon dilation catheter luer is attached to the Inflation Device and the balloon is inflated to desired pressure with sterile water. Monitor the balloon via endoscopy during inflation assessing the diameter, shape, and position of the balloon ensuring that the proximal end of the balloon remains proximal to the stricture.

The balloon can be completely deflated while maintaining an endoscopic view of the balloon using a vacuum. Once visual confirmation of the fully deflated balloon is achieved, the balloon may be removed from the airway.

Indications for Use

The aeris Balloon Dilation Catheter is intended to dilate strictures of the airway.

Substantial Equivalence Claim

Based on comparison of device features, materials, intended use, and performance, the Bryan Medical, aeris Balloon Dilation Catheter is substantially equivalent to the commercially available predicate device Acclarent Inspira AIR approved by the FDA under 510k number K090660 and Boston Scientific CRE approved by the FDA under 510k number K023337. Table 2 shows a substantial equivalence comparison summary of the aeris Balloon Dilation Catheter compared to the predicate devices.

Table 2. Comparison table of aeris Balloon Dilation Catheter characteristics to predicate devices

Attribute	Acclarent Inspira AIR	Boston Scientific CRE	Bryan Medical aeris
A. Intended Use			
A.1 Indications for Use Statement	The Airway Balloon Catheter is an instrument intended to dilate strictures of the airway tree.	The CRE Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.	The aeris Balloon Dilation Catheter is intended to dilate strictures of the airway.
A.2 Labeling	Equivalent in content (label included in Section N)	Equivalent in content (label included in Section N)	Equivalent content (label included in Section N)
A.3 Target Population	All patients meeting intended use and labeling requirements.	All patients meeting intended use and labeling requirements.	All patients meeting intended use and labeling requirements.
A.4 Product code & 21 CFR regulation #	KTI, 874.4680	KTI, 874.4680	KTI, 874.4680
A.5 Contraindications	• Balloon dilation is contraindicated in any patient whose degree of respiratory failure would not allow the patient to tolerate the manipulation required to accomplish balloon dilation. • Balloon dilation is contraindicated in the presence of: ○ significant active bleeding from the site of the proposed dilation ○ and/or presence of a known perforation at the site of proposed dilation ○ and/or presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space.	• Balloon dilation is contraindicated in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate bronchoscopy (rigid or flexible) and/or the manipulation required to accomplish balloon dilation. • Balloon dilation is contraindicated in the presence of: significant active bleeding from the site of the proposed dilatation, and/or presence of a known perforation at the site of proposed dilatation, and/or presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space unless the dilatation was being performed in preparation for the placement of a stent to treat the perforation or fistula.	• Balloon dilation of the airway is contraindicated in any patient whose degree of respiratory failure would not allow the patient to tolerate the manipulation required to accomplish balloon dilation. • Balloon dilation is contraindicated in the presence of: ○ significant active bleeding from the site of the proposed dilation ○ and/or presence of a known perforation at the site of proposed dilation ○ and/or presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space

Table 2 cont.

Attribute	Acclarent Inspira AIR	Boston Scientific CRE	Bryan Medical aeris
B. Technology			
B.1 Balloon Shape at < 2 ATM / Max. Inflation Pressure	Straight body and conical ends / straight body and spherical ends	Straight body and conical ends / straight body and spherical ends	Dog-bone body and conical ends / straight body with spherical ends
B.2 Used with Stylet	Optional	Yes (Guidewire)	Optional
B.3 Radiopaque Markers	No	Yes	Yes
B.4 Patient Contacting Materials	Unknown	Unknown	Nylon balloon, Pebax catheter
B.5 Balloon Diameters	5 mm 7 mm 8.5 mm 10 mm 12 mm 14 mm 16 mm	8 – 9 – 10 mm 10 – 11 – 12 mm 12 – 13.5 – 15 mm 15 – 16.5 – 18 mm 18 – 19 – 20 mm	5 mm 7 mm 8 mm 9 mm 10 mm 12 mm 14 mm 16 mm
B.6 Balloon Working Lengths (mm)	24 for diameters 5, 7, & 8.5 40 for diameters 10, 12, 14, & 16	30 for diameters 8 – 12 55 for diameters 12 – 18 per manufacturer's website	30 for diameters 5 – 10 40 for diameters 12 – 16
B.7 Catheter Outside Diameter (mm)	2.1	2.5	1.55 for diameters 5 – 9 2.34 for diameters 10 – 16
B.8 Catheter Length (cm)	45	75	55
B.9 Deflation Time (Seconds)	≤ 15 & 25 per clearance letter for K110218	Unknown	≤ 15
B.10 Maximum Inflation Pressure	8 – 16 ATM	6 – 9 ATM	10 & 17 ATM
B.11 Flexible	Yes	Yes	Yes
B.12 Shaft Design	Coaxial lumen	Coaxial lumen	Single lumen
B.13 Single-Use	Yes	Yes	Yes
B.14 Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
C. Performance Specifications			
C.1 Inflation Time	Equivalent	Equivalent	≤ 10 seconds
C.2 Insertability	Equivalent	Equivalent	Through equal ID tubing with 10° bend around 4.5" radius
C.3 Removability	Equivalent	Equivalent	Through airway ≤ 60% of balloon diameter

Table 2 cont.

Attribute	Acclarent Inspira AIR	Boston Scientific CRE	Bryan Medical aeris
C.4 Proximal Luer Fitting	Yes	Yes	Yes
C.5 Torqueable	Equivalent	Equivalent	Min. 2 turns
C.6 Bond Force	Unknown	Unknown	Min. 10 N for diameters 5 – 9 Min. 15 N for diameters 10 – 16

The intended use of the aeris Balloon Dilation Catheter is substantially equivalent to the predicate devices in intended use, contraindications, and content of labeling. All devices meet the description set forth by the FDA regulation number 21 CFR Ref. § 874.4680.

The technology incorporated into the aeris Balloon Dilation Catheter is substantially equivalent to the technology for the predicate devices. The major components of these devices include a distally located inflation balloon, a flexible catheter shaft, and proximal luer to which an inflation device may be connected. The catheter shaft can be stiffened with a stylet (guidewire) running axially in an interior lumen. Attached to the catheter shaft under each end of the inflation balloon are radiopaque marker bands similar to the Boston Scientific CRE predicate device. All materials of the aeris Balloon Dilation Catheter were tested for biocompatibility for their intended use.

The inflation balloon sizes of the aeris Balloon Dilation Catheter are equivalent to those of the predicate devices. The predicate device's catalog of sizes includes a 5 mm through 18 mm diameter balloon at inflation pressure with intermediate balloon sizes approximately every 2 millimeters.

The aeris Balloon Dilation Catheter differs from the predicate devices in the design of the balloon. The aeris Balloon Dilation Catheter has hubs proximally and distally located on the balloon which begin to take shape upon inflation creating a dog bone balloon shape. As the pressure approaches the inflation pressure, each balloon end begins to take a spherical end shape. The predicate devices' balloon ends have a conical radius shape at pressures approximately equal to or less than two atmospheres. Above two atmospheres, a spherical end shape, similar to the aeris Balloon Dilation Catheter device takes shape.

The aeris Balloon Dilation Catheter is a single lumen catheter design opposed to a dual lumen design of the predicates. The predicate devices have one lumen for the stylet (guidewire) to run through and a separate inflation lumen. The single aeris Balloon Dilation Catheter lumen is able to serve both of these functions without creating any additional risk.

The performance of the aeris Balloon Dilation Catheter was compared to the predicate devices in the insertability and removability tests. A sample device of each the Acclarent Inspira AIR and Boston Scientific CRE were tested for equivalency. Each predicate device passed the tests, showing equivalency between the aeris Balloon Dilation Catheter and each of the predicates were

applicable. The aeris Balloon Dilation Catheter also shows equivalency to performance specifications of the predicate devices in the proximal luer fitting design. Equivalency of the remaining performance specifications for both predicate devices is unknown at this time due to the specifications being unspecified by the manufactures. The aeris Balloon Dilation Catheter performance specification values confirm there are no increased risks or safety concerns introduced to the patient.

Summary of Testing

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate devices identified in this submission.

Table 3. Summary of baseline bench testing for 5x30mm aeris Balloon Dilation Catheter

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Balloon Working Length	Balloon pressure at 1 ATM	Balloon working length within tolerance	30 ± 1 mm	Pass
Inflation Time	Balloon pressure at 17 ATM	Balloon able to inflate	< 10 seconds	Pass
Deflation Time	Balloon Pressure at 0 ATM	Balloon able to deflate	≤ 15 seconds	Pass
Catheter Fatigue	Balloon inflated 10 times to 17 ATM	10 cycles to recommended use pressure	No evidence of balloon leakage	Pass
Maximum Inflation Pressure	Balloon ruptures	Balloon failure pressure > recommended use pressure	Balloon failure pressure > 17 ATM	Pass
Balloon Hub Measurement	Balloon pressure at 17 ATM	Measure diameter of hub and working length	Hub diameter minus working length diameter < 1 mm	Pass
Balloon Diameter	Balloon pressure at 17 ATM	Balloon diameter within tolerance	5 ± .4 mm	Pass
Insertability	Balloon located	Distal end inserted through 10° bend in tube with 5 mm diameter	No visual signs of kinking or damage done to catheter or stylet	Pass
Removability	Catheter retracted	Distal end withdrawn through 3 mm tube	No visual signs of damage	Pass
Proximal Luer Fitting	Tested	Per ISO 594-1 & 594-2	Meet acceptance criteria of ISO 594-1 & 594-2	Pass
Torqueable	Catheter rotated 2 times	Catheter turned at least 2 times	No visual signs of damage	Pass
Luer/Catheter Shaft Connection	Connection failure	Bond tensile force per ISO 10555	≥ 10 N	Pass

Table 4. Summary of baseline bench testing for 9x30mm aeris Balloon Dilation Catheter

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Balloon Working Length	Balloon pressure at 1 ATM	Balloon working length within tolerance	30 ± .6 mm	Pass
Inflation Time	Balloon pressure at 17 ATM	Balloon able to inflate	< 10 seconds	Pass
Deflation Time	Balloon Pressure at 0 ATM	Balloon able to deflate	≤ 15 seconds	Pass
Catheter Fatigue	Balloon inflated 10 times to 17 ATM	10 cycles to recommended use pressure	No evidence of balloon leakage	Pass
Maximum Inflation Pressure	Balloon ruptures	Balloon failure pressure > recommended use pressure	Balloon failure pressure > 17 ATM	Pass
Balloon Hub Measurement	Balloon pressure at 17 ATM	Measure diameter of hub and working length	Hub diameter minus working length diameter < 1 mm	Pass
Balloon Diameter	Balloon pressure at 17 ATM	Balloon diameter within tolerance	9 ± .4 mm	Pass
Insertability	Balloon located	Distal end inserted through 10° bend in tube with 9 mm diameter	No visual signs of kinking or damage done to catheter or stylet	Pass
Removability	Catheter retracted	Distal end withdrawn through 5 mm tube	No visual signs of damage	Pass
Proximal Luer Fitting	Tested	Per ISO 594-1 & 594-2	Meet acceptance criteria of ISO 594-1 & 594-2	Pass
Torqueable	Catheter rotated 2 times	Catheter turned at least 2 times	No visual signs of damage	Pass
Luer/Catheter Shaft Connection	Connection failure	Bond tensile force per ISO 10555	≥ 10 N	Pass

Table 5. Summary of baseline bench testing for 16x40mm aeris Balloon Dilation Catheter

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Balloon Working Length	Balloon pressure at 1 ATM	Balloon working length within tolerance	40 ± 1 mm	Pass
Inflation Time	Balloon pressure at 10 ATM	Balloon able to inflate	< 10 seconds	Pass
Deflation Time	Balloon Pressure at 0 ATM	Balloon able to deflate	≤ 15 seconds	Pass
Catheter Fatigue	Balloon inflated 10 times to 10 ATM	10 cycles to recommended use pressure	No evidence of balloon leakage	Pass

Table 5 cont.

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Maximum Inflation Pressure	Balloon ruptures	Balloon failure pressure > recommended use pressure	Balloon failure pressure > 10 ATM	Pass
Balloon Hub Measurement	Balloon pressure at 10 ATM	Measure diameter of hub and working length	Hub diameter minus working length diameter < 2 mm	Pass
Balloon Diameter	Balloon pressure at 10 ATM	Balloon diameter within tolerance	16 ± .6 mm	Pass
Insertability	Balloon located	Distal end inserted through 10° bend in tube with 16 mm diameter	No visual signs of kinking or damage done to catheter or stylet	Pass
Removability	Catheter retracted	Distal end withdrawn through 9.6 mm tube	No visual signs of damage	Pass
Proximal Luer Fitting	Tested	Per ISO 594-1 & 594-2	Meet acceptance criteria of ISO 594-1 & 594-2	Pass
Torqueable	Catheter rotated 2 times	Catheter turned at least 2 times	No visual signs of damage	Pass
Luer/Catheter Shaft Connection	Connection failure	Bond tensile force per ISO 10555	≥ 15 N	Pass

Table 6. Summary of transit & 1 year accelerated aging bench testing for 5x30mm aeris Balloon Dilation Catheter

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Balloon Working Length	Balloon pressure at 1 ATM	Balloon working length within tolerance	30 ± 1 mm	Pass
Inflation Time	Balloon pressure at 17 ATM	Balloon able to inflate	< 10 seconds	Pass
Deflation Time	Balloon Pressure at 0 ATM	Balloon able to deflate	≤ 15 seconds	Pass
Catheter Fatigue	Balloon inflated 10 times to 17 ATM	10 cycles to recommended use pressure	No evidence of balloon leakage	Pass
Maximum Inflation Pressure	Balloon ruptures	Balloon failure pressure > recommended use pressure	Balloon failure pressure > 17 ATM	Pass
Balloon Hub Measurement	Balloon pressure at 17 ATM	Measure diameter of hub and working length	Hub diameter minus working length diameter < 1 mm	Pass

Table 6 cont.

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Balloon Diameter	Balloon pressure at 17 ATM	Balloon diameter within tolerance	5 ± .4 mm	Pass
Insertability	Balloon located	Distal end inserted through 10° bend in tube with 5 mm diameter	No visual signs of kinking or damage done to catheter or stylet	Pass
Removability	Catheter retracted	Distal end withdrawn through 3 mm tube	No visual signs of damage	Pass
Proximal Luer Fitting	Tested	Per ISO 594-1 & 594-2	Meet acceptance criteria of ISO 594-1 & 594-2	Pass
Torqueable	Catheter rotated 2 times	Catheter turned at least 2 times	No visual signs of damage	Pass
Luer/Catheter Shaft Connection	Connection failure	Bond tensile force per ISO 10555	≥ 10 N	Pass

Table 7. Summary of transit & 1 year accelerated aging bench testing for 9x30mm aeris Balloon Dilation Catheter

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Balloon Working Length	Balloon pressure at 1 ATM	Balloon working length within tolerance	30 ± .6 mm	Pas
Inflation Time	Balloon pressure at 17 ATM	Balloon able to inflate	< 10 seconds	Pass
Deflation Time	Balloon Pressure at 0 ATM	Balloon able to deflate	≤ 15 seconds	Pass
Catheter Fatigue	Balloon inflated 10 times to 17 ATM	10 cycles to recommended use pressure	No evidence of balloon leakage	Pass
Maximum Inflation Pressure	Balloon ruptures	Balloon failure pressure > recommended use pressure	Balloon failure pressure > 17 ATM	Pass
Balloon Hub Measurement	Balloon pressure at 17 ATM	Measure diameter of hub and working length	Hub diameter minus working length diameter < 1 mm	Pass
Balloon Diameter	Balloon pressure at 17 ATM	Balloon diameter within tolerance	9 ± .4 mm	Pass
Insertability	Balloon located	Distal end inserted through 10° bend in tube with 9 mm diameter	No visual signs of kinking or damage done to catheter or stylet	Pass
Removability	Catheter retracted	Distal end withdrawn through 5 mm tube	No visual signs of damage	Pass

Table 7 cont.

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Proximal Luer Fitting	Tested	Per ISO 594-1 & 594-2	Meet acceptance criteria of ISO 594-1 & 594-2	Pass
Torqueable	Catheter rotated 2 times	Catheter turned at least 2 times	No visual signs of damage	Pass
Luer/Catheter Shaft Connection	Connection failure	Bond tensile force per ISO 10555	≥ 10 N	Pass

Table 8. Summary of transit & 1 year accelerated aging bench testing for 16x40mm aeris Balloon Dilation Catheter

Test	Study Endpoint	Requirement	Acceptance Requirement	Result
Balloon Working Length	Balloon pressure at 1 ATM	Balloon working length within tolerance	40 ± 1 mm	Pass
Inflation Time	Balloon pressure at 10 ATM	Balloon able to inflate	< 10 seconds	Pass
Deflation Time	Balloon Pressure at 0 ATM	Balloon able to deflate	≤ 15 seconds	Pass
Catheter Fatigue	Balloon inflated 10 times to 10 ATM	10 cycles to recommended use pressure	No evidence of balloon leakage	Pass
Maximum Inflation Pressure	Balloon ruptures	Balloon failure pressure > recommended use pressure	Balloon failure pressure > 10 ATM	Pass
Balloon Hub Measurement	Balloon pressure at 10 ATM	Measure diameter of hub and working length	Hub diameter minus working length diameter < 2 mm	Pass
Balloon Diameter	Balloon pressure at 10 ATM	Balloon diameter within tolerance	16 ± .6 mm	Pass
Insertability	Balloon located past curve	Catheter inserted through 10° bend in tube with 16 mm diameter	No visual signs of kinking or damage done to catheter or stylet	Pass
Removability	Catheter retracted from tubing	Distal end withdrawn through 9.6 mm tube	No visual signs of damage	Pass
Proximal Luer Fitting	Tested	Per ISO 594-1 & 594-2	Meet acceptance criteria of ISO 594-1 & 594-2	Pass
Torqueable	Catheter turned 2 times	Catheter turned at least 2 times	No visual signs of damage	Pass
Luer/Catheter Shaft Connection	Connection failure	Bond tensile force per ISO 10555	≥ 15 N	Pass

Table 9. Summary of predicate devices performance testing for an 8.5x24mm Inspira AIR and 15x30mm CRE Pulmonary.

Test	Study Endpoint	Requirement	Acceptance Requirement	Result	
				Inspira AIR	CRE Pulmonary
Inflation Time	Balloon pressure at max. inflation pressure	Balloon able to inflate	< 10 seconds	Pass	Pass
Insertability	Balloon located past curve	Catheter inserted through 10° bend in tube with balloon size diameter	No visual signs of kinking or damage done to catheter or stylet	Pass	Pass
Removability	Catheter retracted from tubing	Distal end withdrawn through tube with ID 60% of balloon size	No visual signs of damage	Pass	Pass
Torqueable	Catheter turned 2 times	Catheter turned at least 2 times	No visual signs of damage	Pass	Pass

Table 10. Summary of comparison test between 9x30mm aeris Balloon Dilation Catheter 15x30mm CRE Pulmonary.

Test	Study Endpoint	Requirement	Acceptance Requirement	Result	
				Inspira AIR	CRE Pulmonary
Radiopacity	X-ray performed	The balloon will have marker bands, one under each balloon neck, that are visible under fluoroscopy	Equivalent visibility of the aeris marker bands to the predicate devices	N/A	Equivalent

Table 11. All materials, biocompatibility testing summary.

Test Description	Acceptance Criteria	Results
L929 MEM Elution Cytotoxicity	Test article must have a reactivity grade of mild or less (≤ 2)	There was no biological reactivity (Grade 0) of the cells exposed to the test article extract.
Guinea Pig Maximization Sensitization	Test article must have a reaction sensitivity grade of no visible change (Grade 0)	There was no sensitization response (Grade 0) in the test articles.
Acute Systemic Toxicity	Animals treated with test article extract must not show signs indicative of toxicity.	None of the test article extract treated animals observed with clinical signs consistent with toxicity.
Intracutaneous Irritation	Tissue reaction to the test article to control dermal observation score is ≤ 1.	Differences in mean test and control scores of extract dermal operations were less than 1.