Respicardia

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5.0 510(K) SUMMARY

OCT 17 2013

Device Name: Respiguide Delivery System

510(k) Owner: Respicardia, Inc.
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Date Prepared:	15 October 2013
Device Tradename:	Respiguide Delivery System
Device Common or Usual Name:	Guiding Catheter and Angiographic Catheter
Classification Information:	Class II
Regulation Numbers:	21 CFR 870.1250
Product Codes:	DQY, DQO
Classification Names:	Percutaneous Catheter, Diagnostic Catheter
Review Panel:	Cardiovascular

Predicate Device 1: Merit Medical Systems, Inc. 6F Concierge Guide Catheter (K121051)

Predicate Device 2: Merit Medical Systems, Inc. 5F Impress Angiographic Catheter (K053171, K093004)

510(k) Summary: K130378

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Device Description: The Respiguide Delivery System is a single use catheter system consisting of a 7F slittable outer guide catheter and a 5F inner angiographic catheter. Both catheters consist of stainless steel wirebraid reinforced shafts, molded hubs, and flexible and tapered distal tips. The inner and outer catheter shafts contain the wire-braiding for torque performance. The tapered and flexible distal tips of the inner and outer catheters are designed to reduce the potential for vessel trauma. The outer guide catheter is offered with distal tips that are straight or have 90- or 120-degree angles. The inner angiographic catheter is offered with distal tips that are either straight or have a "KA2" shape (a gentle 60 degree shape). The shapes are designed to facilitate maneuvering of interventional/diagnostic devices into peripheral vascular systems.

See the product matrix table (Table 1a) that identifies the distal shape and the packaging configuration for each model. Tables 1b and 1c illustrate the distal shapes referenced in Table 1a.

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Table 1. a) Respiguide Delivery System Product Matrix

System Model No.	Outer Guide Catheter		Inner Angiograhic Catheter	
	Length	Distal Shape	Length	Distal Shape
7000-S	35-cm	Straight	65-cm	Straight
7090-S		90°		
7120-S		120°		
7000-K		Straight	40-cm	KA2
7090-K		90°		
7120-K		120°		

Table 1. b) Outer Guide Catheter Tip Shapes

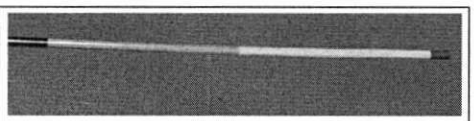
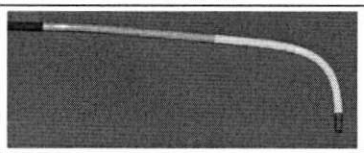
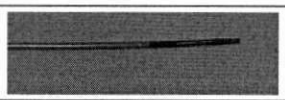
Straight	
90°	
120°	

Table 1. c) Inner Angiographic Catheter Tip Shapes

Straight	
KA2	

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Intended Use and Comparison to Predicate Device:

The Respicardia, Inc. Respiguide Delivery System consists of a 7F outer guide catheter and a 5F inner angiographic catheter.

The 7F outer guide catheter is a modification to a predicate device, the 6F Concierge Guide Catheter (K121051), manufactured by Merit Medical Systems, Inc. (South Jordan, UT), and distributed as an individual guide catheter. The 5F inner angiographic catheter is identical in all respects (except for a logo on the hug) to the 5F Impress Angiographic Catheter (K053171, K093004), also manufactured by Merit Medical Systems, Inc., and distributed as an individual angiographic catheter.

The intended use statements for the catheters in the Respiguide Delivery System are as follows:

> *Outer Guide Catheter: The Guide Catheter is intended for use for intravascular introduction of interventional/diagnostic devices into the peripheral vascular systems.*
>
> *Inner (Angiographic Catheter): Angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.*

These intended use statements for the Respiguide Delivery Catheter do not include an intended use in the coronary vasculature, but are otherwise identical to the intended use statements of Predicate Device 1 (K121051); additionally, the intended use statements are identical to those of Predicate Device 2 (K053171, K093004).

Figure 1 below shows a photograph of the Respiguide Delivery System and the Predicate Devices 1 and 2.

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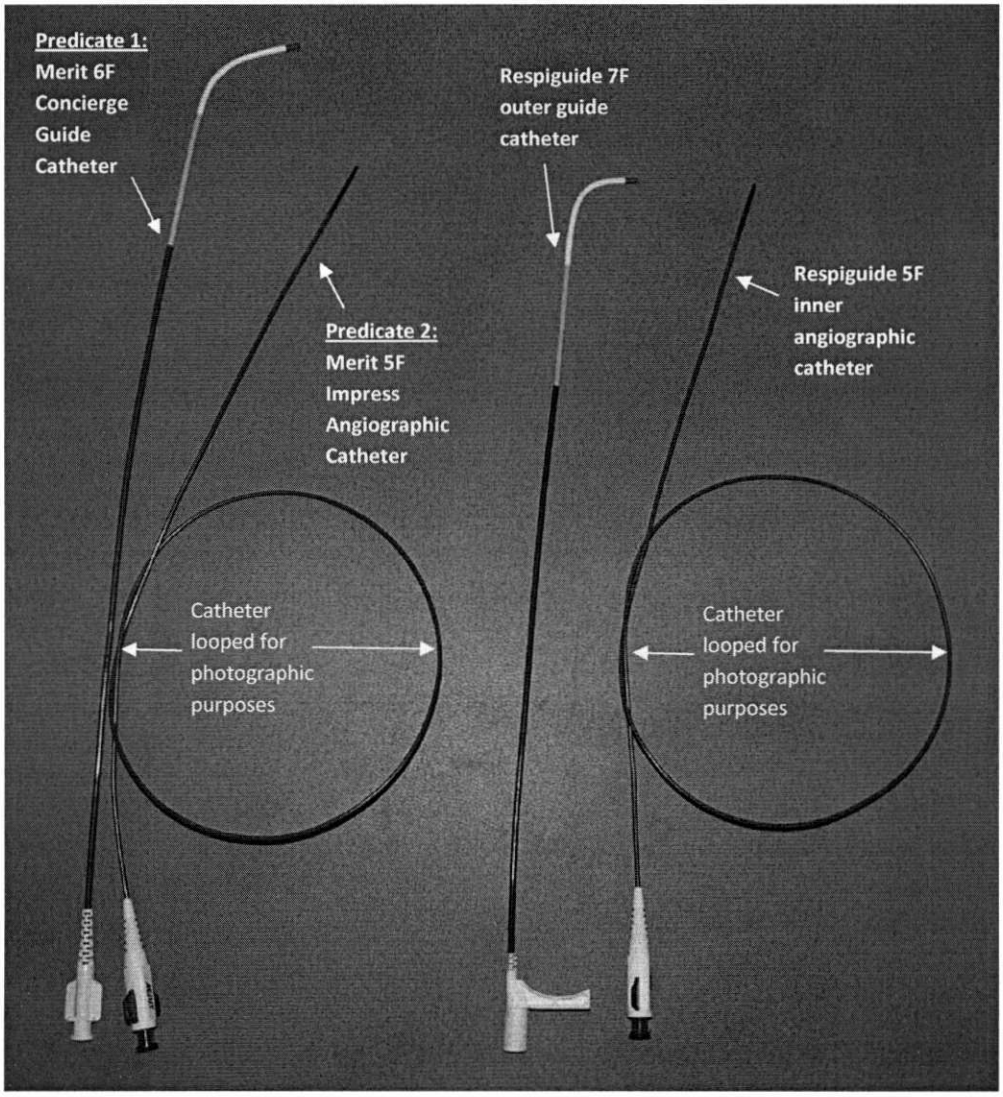

Figure 1. Photograph of Merit Medical Systems, Inc. predicate devices on left, Respicardia, Inc. Respiguide Delivery System devices on right.

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The Respiguide Delivery System contains minimal modifications from the predicate devices. The Respiguide 7F outer guide catheter differs from the predicate Merit 6F Concierge Guide Catheter in the following ways:

1. Round stainless steel wirebraid is used instead of flat stainless steel wirebraid in the Merit 6F Concierge guide catheter. The round wire is to facilitate catheter slitting with a catheter slitter.
2. The hub shape is modified to accommodate a hemostatic valve and to be slittable with a catheter slitter. The Merit 6F Concierge guide catheter uses a standard Luer connector which is not slittable. Note: the hubs on both the Respiguide 7F outer guide catheter and the Merit 6F Concierge Guide Catheter are the identical material.
3. The tip tapers to a smaller diameter than the Merit 6F Guide Catheter. This is so the Respiguide 7F outer guide catheter fits the outer diameter of the Respiguide 5F inner angiographic catheter without any gaps or spaces.
4. Straight, 90 degree, and 120 degree tip shapes are provided for the Respiguide 7F outer guide catheter, whereas the Merit 6F Guide Catheter is offered with many tip shapes as shown in Figure 6. The "AL2" and EG" shapes are similar to the Respiguide 90 and 120 degree bends.
5. The length of the catheter is 35cm, whereas the length of the Merit 6F Guide Catheter is offered in a length of 100cm.
6. The diameter of the Respiguide catheter is 7F, whereas the diameter of the predicate Merit 6F guide catheter is 6F.

The Respiguide 5F inner angiographic catheter differs from the predicate Merit 5F Impress Angiographic Catheter in the following way:

1. The hub is printed with a "Respicardia" logo instead of a "Merit" logo.

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Summary of Performane Testing – Clinical:

No clinical testing is being used to establish substantial equivalence.

Summary of Performance Testing – Animal:

No animal testing is being used to establish substantial equivalence.

Summary of Perfomance Testing – Bench:

The objective of the performance testing was to ensure the Respiguide Delivery System, 7F outer guide catheter and 5F inner angiographic catheter, met Respicardia Inc. internal specifications and to ensure substantial equivalence to the predicate devices. This includes both design verification and design validation testing. Design Validation testing was performed because the 7F guide catheter has incorporated slittability and the ability to connect to a hemostatic valve. These features were not present on the predicate Merit 6F Guide Catheter therefore they warrant design validation.

Design verification testing was performed in-house by Respicardia, Inc. and by a contract testing facility DDL, Inc. (Eden Prairie, MN). Section 18, Performance Testing – Bench, provides further details. Below is a list of testing performed:

- Surface and cleanliness
- Dimensions
- Fit with 5F Impress Angiographic Catheter and SafeSheath Sealing Adaptor
- Fluid Leakage
- Air Leakage
- Torque
- Bending
- Shaft Slit Force
- Hub Slit Force
- Kink Resistance
- Force at Break
- Corrosion Resistance

Design Validation Testing (Human Factors Testing) was performed in-house by Respicardia, Inc. and consisted of physician experience testing with cadavers and glass models. Section 18, Performance Testing – Bench, provides futher details. This testing was a qualitative anlaysis in which physicians were asked to use the

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Respiguide Delivery System and evaluate the performance of the following characteristics:

- 7F outer guide catheter shaft length was appropriate
- 7F outer guide catheter torque-ability (ability to transmit torque through the catheter shaft and aim the tip of the catheter as desired)
- 7F outer guide catheter tip angle was appropriate
- 7F outer guide catheter tip shape was appropriate
- 7F outer guide catheter fit with 5F inner angiographic catheter was smooth and worked well as a system
- 7F outer guide catheter was slittable with a catheter slitter
- 5F inner angiographic catheter length was appropriate
- 5F inner angiographic catheter distal shape was appropriate

The design verification and validation testing indicated the Respiguide Delivery System met Respicardia, Inc. internal requirements and is substantially equivalent.

Summary of Perfomance Testing – Shelf-Life:

Shelf life is supported by: 1) Packing integrity testing and 2) Three (3) year accelerated aging. These tests were performed to ensure that both the packaging and the Respiguide Delivery System met specifications after environmental conditioning, distribution conditioning, and accelerated aging. Real time conditioning is currently underway. Section 14, Sterilization and Shelf-life, provides further details.

Summary of Performance Testing – Sterilization:

A TIR 28 sterilization adoptiong was performed on the Respidguide Delivery System (including the 7F outer guide catheter, the 5F inner guide catheter, and the packaging) to ensure that the Respiguide Delivery System can be adopted into the Merit Medical Systems, Inc. sterilization process. This testing indicated that the Respiguide Delivery System was successfully sterilized using the same sterilization process as the predicate devices. Section 14, Sterilization and Shelf-life, provides further details.

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 17, 2013

Respicardia
C/O Bonnie Labosky
12400 Whitewater Drive
Suite 150
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Re: K130378
Trade/Device Name: Respiguide Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO
Dated: September 16, 2013
Received: September 17, 2013

Dear Ms. Labosky:

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 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. 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: *K130378*

Device Name:

Respiguide Delivery System

Indications for Use:

Respiguide outer guide catheter: The guide catheter is intended for use for intravascular introduction of interventional/diagnostic devices into peripheral vascular systems.

Respiguide inner (angiographic) catheter: Angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

Prescription Use: X AND/OR Over-the-Counter Use: _____
(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 Device Evaluation (ODE)

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