



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

July 27, 2016

Intuit Medical Products, LLC
Mr. Jack Griffis
VP, Research & Development
6018 Eagles Rest Trail
Sugar Hill, GA 30518

Re: K153484

Trade/Device Name: Dillard Airway Dilatation System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: June 22, 2016
Received: June 29, 2016

Dear Mr. Griffis:

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" (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 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

510(k) Number (if known)

K153484

Device Name

Airway Dilatation System

Indications for Use (Describe)

The Dillard Airway Dilatation System is intended to dilate strictures of the airway trees.

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.

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

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

The burden time for this collection of information is estimated to average 79 hours 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
PRASStaff@fda.hhs.gov

"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 number."



510(k) Summary

510(k) Number: K153484

Date Revised: July 25th, 2016

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

- A. Submitter:
Intuit Medical Products (IMP), LLC
6018 Eagles Rest Trail
Sugar Hill, Georgia 30518

- B. Company Contact:
Jack Griffis
Vice President, Research & Development
(404) 583-6889 (direct)
jgriffis@intuitmedicalproducts.com

- C. Device Information:
Trade Name: Dillard Airway Dilatation Catheter
Common Name: Airway Dilatation System

- D. Classification: Bronchoscope (flexible or rigid) and accessories
 KTI, 21 CFR 874.4680
 Class II

- E. Predicate Device:
Acclarent Airway Dilation Catheter (Inspira[®]), K090660

- F. Physical Description:
The Dillard Airway Dilatation System includes a balloon catheter whose working length is 25cm or 100cm, and is available in balloon diameters from 5mm to 12mm and balloon lengths of 20mm and 40mm. The balloon component of the catheter has radiopaque markers to assist with radiographic positioning (as applicable). The proximal end of the device is a common catheter design consisting of a plastic hub and strain relief. The hub is used to inflate the balloon and the luer connector integrated into the hub is compatible with standard inflation devices. A second lumen within the catheter, intended for guidewire use, extends through the central lumen back to the proximal hub and through the distal tip. All catheters and accessories are supplied sterile and intended for single use.

NOTE: the proposed device is identical to that previously cleared under K143738, with the exception of additional balloon sizes and indication for use in airway dilatation.

G. Indications for Use:

The Dillard Airway Dilatation System is intended to dilate strictures of the airway tree.

H. Comparison of Characteristics / Performance Testing / Substantial Equivalence:

The Dillard Airway Dilatation System is substantially equivalent to the predicate device in intended use, indications for use, fundamental scientific technology, and important performance specifications. Refer to the Table below for a summary:

Parameter	DAS Air Balloon Catheter (Proposed)	Acclarent Inspira® AIR Balloon Catheter (Predicate, K090660)
Indications for Use	Intended to dilate strictures of the airway tree.	
Principle of Operation	<i>Operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end</i>	
Guidewire Style	<i>OTW</i>	<i>OTW and Integrated</i>
Guidewire Compatibility	<i>OTW: 0.035"</i>	<i>Integrated: Unknown OTW: 0.035"</i>
Catheter Lengths	<i>25cm and 140cm</i>	<i>30cm</i>
Balloon Lengths	<i>20 and 40mm</i>	<i>24 and 40mm</i>
Balloon Diameters	<i>5.0 thru 12.0mm</i>	<i>5.0 thru 16.0mm</i>
Nominal Inflation Pressure	<i>6 ATM for all catheters</i>	<i>6 ATM</i>
MAX Recommended Inflation Pressure	<i>12 ATM for balloon diameters 5.0 thru 10.0mm 10 ATM for balloon diameters 11.0 and 12.0mm</i>	<i>16 ATM for balloon diameters 5.0 thru 7.0mm 12 ATM for balloon diameters 8.0 thru 11mm 10 ATM for balloon diameters 12.0 thru 14.0mm 8 ATM for balloon diameter 16.0mm</i>
Single Use?	<i>Yes</i>	
Sterilization Method	<i>100% Ethylene Oxide gas</i>	
Packaging	<i>Tyvek-Mylar Pouch, Protective Tube, Stylet</i>	
Balloon Material	<i>Nylon</i>	<i>Nylon blend</i>
Catheter Materials	<i>Nylon, Pebax/Plexar/HDPE Tri-Extrusion, Platinum-Iridium Marker Bands</i>	<i>Polymer Extrusions (unknown), Platinum-Iridium Marker Bands</i>

In addition, the device was subjected to the following performance tests to support the assertion of substantial equivalence:

- Dimensional specifications (including compliance)
- Joint separation strength
- Compatibility with (standard) accessories
- Balloon burst pressure



- Inflation and deflation times
- Balloon cycle fatigue
- Balloon deflation challenge testing
- Biocompatibility Testing in Compliance with the ISO 10993-1 and the FDA Bluebook Memorandum (G-95-1) as follows (and where applicable):
 - Cytotoxicity
 - Sensitization (Guinea Pig Maximization)
 - Mucosal (oral) Irritation

No new questions of safety or effectiveness were identified during device testing; therefore, the Dillard Airway Dilatation System is considered substantially equivalent to the predicate device.



Jack Griffis
Vice President, Research & Development

