DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 25, 2016

DeRoyal Industries, Inc.
Elizabeth Wheeler
Senior Regulatory Affairs Specialist
200 DeBusk Lane
Powell, TN 37849

Re: K152978
Trade/Device Name: DeRoyal Angiography Kits
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT
Dated: February 15, 2016
Received: February 16, 2016

Dear Elizabeth Wheeler:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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,

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

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)*
K152978

Device Name
DeRoyal Angiography Kits

Indications for Use *(Describe)*

DeRoyal Angiography Kits are intended for use by licensed physicians. The intended use of individual medical products assembled in these kits will not be changed from the manufacturer's original intended use. These kits are assembled of devices used during cardiac catheterization laboratory procedures such as cardiac catheterization, angiography, arteriogram, etc.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Corporate
200 DeBusk Lane
Powell, TN 37849 USA
865.938.7828
800.251.9864
www.deroyal.com

DeRoyal Industries, Inc.
Traditional 510(K) Submission – Angiography Kits
October 8, 2015

510(k) Summary

Original Date prepared:	October 8, 2015
Revised Date:	March 22, 2016
510(k) Owner:	DeRoyal Industries, Inc. 200 DeBusk Lane Powell, TN 37849 Owner/Operator #1044833
510(k) Contact:	Elizabeth Wheeler Senior Regulatory Affairs Specialist 865-362-2333 ewheeler@deroyal.com
Manufacturer:	DeRoyal Industries, Inc. 1501 East Central Ave. LaFollette, TN 37766 FDA Registration Number: 3005011024
Trade Name:	DeRoyal Angiography Kits
Common Name:	Angiography Kits
Classification:	Angiographic Injector and Syringe
Device Product Code:	**Primary:** DXT
Substantial Equivalency:	Navilyst Medical Angiography Syringe Kits – K933846 Merit Medical Systems, Inc. Merit Custom Kits – K913682

Indications for Use:
DeRoyal Angiography Kits are intended for use by licensed physicians. The intended use of individual medical products assembled in these kits will not be changed from the manufacturer's original intended use. These kits are assembled of devices used during cardiac catheterization laboratory procedures such as cardiac catheterization, angiography, arteriogram, etc.

Device Description:
DeRoyal Angiography Kits (sometimes referred to as Challenge Kit or Standard Heart and Vascular Kit in this submission) are kits assembled of legally marketed medical devices- either exempt, marketed according to a 510(k), or pre-amendment devices-

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intended for prescription use during procedures occurring in the cardiac catheterization laboratory. The kits are assembled using DeRoyal and other manufacturer's medical devices. DeRoyal purchases the medical device components assembled in these kits bulk, non-sterile. DeRoyal assembles the kits, packages, and sterilizes the kits.

The DeRoyal Angiography Kit components intended use are unchanged from that of the original manufacturers intended use. These kits are assembled according to customer specifications who specify the contents, quantity of devices and placement of the devices in the kit. DeRoyal customers may request that certain components be bonded prior to placement in the kit for convenience purposes in reducing set up time prior to a procedure. The devices used in the DeRoyal Angiography Kits are standard items used in catheterization laboratory procedures. These kits are assembled in a controlled manufacturing environment and are sterilized by Ethylene Oxide.

DeRoyal Angiography Kits are substantially equivalent to kits and/or trays marketed by Navilyst Medical and Merit Medical. The predicate kits marketed are comprised of similar devices from other manufacturers, undergo the same assembly procedures including bonding of certain devices and they have the same intended use.

Summary of Technological Characteristics:

Feature	**Predicate Device** **Navilyst Medical-Angiography Syringe Kits** **K933846**	**Predicate Device** **Merit Medical Systems, Inc.-Merit Custom Kit** **K913682**	**Proposed Device** **DeRoyal Angiography Kit**
Intended Use	Procedures occurring in Cardiac Catheterization Lab	Procedures occurring in Cardiac Catheterization Lab	Same as predicate
Contents	Various legally marketed devices	Various legally marketed devices	Same as predicate
Assembly	Bonded and non-bonded components	Bonded and non-bonded components	Same as predicate
Design	Custom contents using currently marketed devices and assembled at customer request	Custom contents using currently marketed devices and assembled at customer request	Same as predicate
Bonding Agents	Methylene Chloride or Cyclohexanone or Methylene Chloride 50% and Cyclohexanone 50%	Methylene Chloride or Cyclohexanone or Methylene Chloride 50% and Cyclohexanone 50%	Same as predicate

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Feature	Predicate Device Navilyst Medical-Angiography Syringe Kits K933846	Predicate Device Merit Medical Systems, Inc.-Merit Custom Kit K913682	Proposed Device DeRoyal Angiography Kit
Sterility	Ethylene Oxide	Ethylene Oxide	Same as predicate
Packaging	Sterile Pouch	Sterile Pouch	Same as predicate

Basis for Substantial Equivalence:
DeRoyal Angiography Kits are kits assembled of legally marketed medical devices- either exempt, marketed according to a 510(k), or pre-amendment devices-intended for prescription use during procedures occurring in the cardiac catheterization laboratory. The kits are assembled using DeRoyal and other manufacturer's medical devices. DeRoyal purchases the medical device components assembled in these kits bulk, non-sterile. DeRoyal assembles the kits, packages, and sterilizes the kits.

DeRoyal Angiography Kits are substantially equivalent to kits and/or trays marketed by Navilyst Medical and Merit Medical. The predicate kits marketed are comprised of similar devices from other manufacturers, undergo the same assembly procedures including bonding of certain devices and they have the same intended use. The proposed device/kits do not raise any new issues of safety and effectiveness.

Clinical Studies:
Clinical Testing was not performed for this device as it is not a high risk, class III device for which clinical evaluations are needed.

Summary of Testing Performed:
Bench testing was performed to demonstrate the three methods of bonding used in the assembly of kit components for the DeRoyal Angiography Kits to one another using solvent agents to secure bonds. The validation was conducted on the DeRoyal Angiography Kit 77-400980 after the bonding process to insure there is not a negative effect on the kit. The tests performed were identified as visual, pull test, and air leak test.

The DeRoyal Angiography Kits are manufactured with materials that meet the ISO 10993-1: Biological Evaluation of Medical Device-Part 1: Evaluation and testing within a risk management process for their appropriate contact level. The materials used in these devices are classified as either non-patient contacting or blood path, indirect, externally communicating devices of less than 24 hours limited patient contacting. Biocompatibility testing was completed through the fluidic path of the bonded components only. The following Biocompatibility Testing was conducted:

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- ISO 10993-1: Biological Evaluation of Medical Devices-Evaluations of Medical Devices
- ISO 10993-5: Biological Evaluation of Medical Devices-Part 5-In Vitro Cytotoxicity
- ISO 10993-10: Biological Evaluation of Medical Devices-Part 10- Tests for Skin Irritation and Sensitization
- ISO 10993-11: Biological Evaluation of Medical Devices-Part 11- Tests for Systemic Toxicity
- ASTM F756: Standard Practice for Assessment of Hemolytic Properties of Materials

Biocompatibility for the limited patient contacting materials have been established through history of use in the individual medical device components of the kits as cleared through their original manufacturers 510(k) or are exempt from the 510(k) process based on their classification.