



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

October 27, 2016

Cook Incorporated  
Jennifer Allman  
Regulatory Affairs Specialist  
750 Daniels Way  
Bloomington, Indiana 47402

Re: K161822  
Trade/Device Name: Torcon NB Advantage Catheters  
Regulation Number: 21 CFR 870.1200  
Regulation Name: Diagnostic Intravascular Catheter  
Regulatory Class: Class II  
Product Code: DQO  
Dated: September 29, 2016  
Received: September 30, 2016

Dear Jennifer Allman:

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,

  
Brian D. Pullin -S

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

Enclosure

## Indications for Use

510(k) Number (if known)

K161822

Device Name

Torcon NB® Advantage catheters

Indications for Use (Describe)

The Torcon NB® Advantage Catheters are intended for use in the peripheral and coronary vascular system including the carotid arteries in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.

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.\***

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K161822

## 510(k) SUMMARY

**Submitted By:** Jennifer Allman  
Cook Incorporated  
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Bloomington, IN 47404  
Phone: (812)335-3575 x104280  
Fax: (812)332-0281  
Date Prepared: 26 October 2016

### Device:

Trade Name: Torcon NB<sup>®</sup> Advantage Catheters – K161822  
Common Name: Diagnostic Intravascular Catheter  
Classification Name: Catheter, Diagnostic Intravascular  
DQO (21 CFR § 870.1200)

Class: Class II  
Device Panel: Cardiovascular

### Indications for Use:

The Torcon NB<sup>®</sup> Advantage Catheters are intended for use in the peripheral and coronary vascular system including the carotid arteries in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.

### Predicate Device:

Cook Incorporated's Torcon NB<sup>®</sup> Advantage Catheters have an identical intended use to the predicate device, Beacon Tip Torcon NB<sup>®</sup> Advantage Catheters and Torcon NB<sup>®</sup> Advantage Catheters (K133130). Additionally, the principles of operation, technological characteristics, materials, and manufacturing processes of the Torcon NB<sup>®</sup> Advantage Catheters have not changed from the design previously cleared for the predicate device, Beacon Tip Torcon NB<sup>®</sup> Advantage Catheters and Torcon NB<sup>®</sup> Advantage Catheters (K133130). The results of this comparison of the subject device to the predicate device support a determination of substantial equivalence.



### **Comparison to Predicate Devices:**

It has been demonstrated that the Torcon NB<sup>®</sup> Advantage Catheters are comparable to the predicate device (K133130) in terms of design, intended use, materials, fundamental technology, and principles of operation.

### **Device Description:**

Torcon NB<sup>®</sup> Advantage Catheters are selective angiographic catheters manufactured with a thinwall radiopaque nylon material, having a blue hue. The nylon catheter is constructed with stainless steel braiding and a large internal diameter. These catheters are manufactured with a soft distal tip which may or may not be tapered at the distal tip and are manufactured in a variety of distal curve configurations (DAV, MPA, KMP, etc.) to facilitate selective angiography.

Torcon NB<sup>®</sup> Advantage Catheters are available in 4.1 to 7.0 French, and nominal lengths measuring 35 to 125 centimeters. The catheter tips may be tapered at the distal tip to accept a 0.035 or 0.038 inch diameter wire guides. Alternately, the subject device may have a non-tapered tip or may be manufactured with a closed distal end. The subject devices are manufactured with sideport quantities ranging from zero to twelve per device.

Torcon NB<sup>®</sup> Advantage Catheters are for use in angiographic procedures as a conduit for the delivery of contrast media to assist physicians in the diagnosis and management of occlusions or stenoses and in placement of medical devices. The catheters are designed for percutaneous introduction into the vascular system over an appropriately sized wire guide.

### **Test Data:**

Based on the risk analysis, no new performance testing was deemed warranted to support a determination of substantial equivalence to the predicate device. Additionally, there are no new materials that would affect the biocompatibility profile.

### **Technological Characteristics:**

There are no technological characteristic differences between the predicate device, Beacon Tip Torcon NB<sup>®</sup> Advantage Catheters and Torcon NB<sup>®</sup> Advantage Catheters (K133130) and the subject device.