



Food and Drug Administration
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April 8, 2016

Cook Incorporated
Mr. Steven Lawrie, MS, MA, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K160223

Trade/Device Name: VentriClear Ventricular Drainage Catheter Set with Cook Spectrum Antibiotic Impregnation and VentriClear II Ventricular Drainage Catheter

Regulation Number: 21 CFR 882.4100

Regulation Name: Ventricular Catheter

Regulatory Class: Class II

Product Code: NHC

Dated: March 9, 2016

Received: March 10, 2016

Dear Mr. Steven Lawrie:

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,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160223

Device Name

VentriClear Ventricular Drainage Catheter Set with Cook Spectrum Antibiotic Impregnation
VentriClear II Ventricular Drainage Catheter

Indications for Use (Describe)

The VentriClear Ventricular Drainage Catheter Set with Cook Spectrum Antibiotic Impregnation and the VentriClear II Ventricular Drainage Catheter have been designed for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume.

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

**VentriClear[®] Ventricular Drainage Catheter Set
 with Cook[®] Spectrum[®] Antibiotic Impregnation
 VentriClear[®] II Ventricular Drainage Catheter
 21 CFR §882.4100**

Date Prepared: February 23, 2016

Submitted By:

Applicant: Cook Incorporated
 Contact: Steven Lawrie
 Applicant Address: 750 Daniels Way
 Bloomington, IN 47404
 Contact Phone Number: (812) 335-3575 x104518
 Contact Fax Number: (812) 332-0281

Device Information

Trade Name: **VentriClear[®] Ventricular Drainage Catheter Set
 with Cook[®] Spectrum[®] Antibiotic Impregnation
 VentriClear[®] II Ventricular Drainage Catheter**
 Common Name: Ventricular Catheter
 Classification Name: Catheter, Ventricular (Containing Antibiotic Or
 Antimicrobial Agents)
 NHC (21 CFR §882.4100)
 Class: Class II

Predicate Devices:

- K011812, Spectrum[®] Ventricular Catheter
- K071640, VentriClear[®] II Ventricular Drainage Catheter Set

Device Description:

The VentriClear[®] Ventricular Drainage Catheter Set with Cook[®] Spectrum[®] Antibiotic Impregnation consists of a VentriClear[®] Ventricular Drainage catheter and other components that are used to facilitate the procedure. The VentriClear[®] Ventricular Drainage Catheter is a 9 French catheter designed with a radiopaque tip which aids in radiographic recognition and has a closed-end configuration with 16 standard and 16 small sideports. The VentriClear[®] Ventricular Drainage Catheter has markings at 1 cm



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increments to aid in determining depth and ease of placement and is 33 cm in length. The VentriClear[®] Ventricular Drainage Catheter consists of silicone elastomer impregnated with the antimicrobial agents minocycline and rifampin.

The VentriClear[®] II Ventricular Drainage Catheter consists of a VentriClear[®] II Ventricular Drainage catheter and other components that are used to facilitate the procedure. The VentriClear[®] II Ventricular Drainage Catheter is a 9 French catheter designed with a radiopaque tip which aids in radiographic recognition and has a closed-end configuration with 16 sideports. The VentriClear[®] II Ventricular Drainage Catheter has markings at 1 cm increments, starting at the 3 cm mark and extending to 33 cm, to aid in determining depth and ease of placement and is 33 cm in length. The VentriClear[®] II Ventricular Drainage Catheter consists of silicone elastomer impregnated with the antimicrobial agents minocycline and rifampin.

Indications for Use:

The VentriClear[®] Ventricular Drainage Catheter Set with Cook[®] Spectrum[®] Antibiotic Impregnation and the VentriClear[®] II Ventricular Drainage Catheter have been designed for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume.

The indications for use are same as the predicate devices, the Spectrum[®] Ventricular Catheter (K011812) and the VentriClear[®] II Ventricular Drainage Catheter Set (K071640).

Comparison to Predicate:

The VentriClear[®] Ventricular Drainage Catheter Set with Cook[®] Spectrum[®] Antibiotic Impregnation and the VentriClear[®] II Ventricular Drainage Catheter are identical to the predicate devices, the Spectrum[®] Ventricular Catheter (K011812) and the VentriClear[®] II Ventricular Drainage Catheter Set (K071640), with the exception of the addition of a contraindication. The following contraindication is added to the IFU for the VentriClear[®] Ventricular Drainage Catheter Set:

“VentriClear catheters are contraindicated for use in pregnant women.”

Additionally, the following contraindication is added to the IFU for the VentriClear[®] II Ventricular Drainage Catheter:

“The VentriClear II is contraindicated for use in pregnant women.”



Table 1 below provides a detailed comparison of the subject and predicate devices.

Table 1: Comparison Table

	PREDICATE DEVICES		PROPOSED DEVICE
	Spectrum® Ventricular Catheter (K011812)	VentriClear® II Ventricular Drainage Catheter Set (K071640)	VentriClear® Ventricular Drainage Catheter Set with Cook® Spectrum® Antibiotic Impregnation and the VentriClear® II Ventricular Drainage Catheter
Regulation Number	882.4100	882.4100	882.4100
Product Code	NHC	NHC	NHC
Classification	Catheter, Ventricular (Containing Antibiotic Or Antimicrobial Agents)	Catheter, Ventricular (Containing Antibiotic Or Antimicrobial Agents)	Catheter, Ventricular (Containing Antibiotic Or Antimicrobial Agents)
Indications for Use	For obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume.	For obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume.	Identical
Contraindications	<ul style="list-style-type: none"> This device is contraindicated in patients having allergy or history of allergy to tetracyclines or rifampin. NOTE: Because the VentriClear Ventricular Drainage Catheter is impregnated with a combination of the antimicrobial agents minocycline (a derivative of tetracycline) and rifampin (a derivative of rifamycin B), their associated contraindications, warnings and precautions (Physician's Desk Reference) should be considered when using this device,	<ul style="list-style-type: none"> This device is contraindicated in patients having allergy or history of allergy to tetracyclines or rifampin. NOTE: Because the VentriClear Ventricular Drainage Catheter is impregnated with a combination of the antimicrobial agents minocycline (a derivative of tetracycline) and rifampin (a derivative of rifamycin B), their associated contraindications, warnings and precautions (Physician's Desk Reference) should be considered when using this device,	<ul style="list-style-type: none"> This device is contraindicated in patients having allergy or history of allergy to tetracyclines or rifampin. NOTE: Because the VentriClear Ventricular Drainage Catheter is impregnated with a combination of the antimicrobial agents minocycline (a derivative of tetracycline) and rifampin (a derivative of rifamycin B), their associated contraindications, warnings and precautions (Physician's Desk Reference) should be considered when using this device,



Table 1: Comparison Table (continued)

		PREDICATE DEVICES		PROPOSED DEVICE
		Spectrum® Ventricular Catheter (K011812)	VentriClear® II Ventricular Drainage Catheter Set (K071640)	VentriClear® Ventricular Drainage Catheter Set with Cook® Spectrum® Antibiotic Impregnation and the VentriClear® II Ventricular Drainage Catheter
Contraindications (continued)		although there have been no reports of detected systemic levels of minocycline or rifampin in patients receiving a VentriClear Catheter.	although there have been no reports of detected systemic levels of minocycline or rifampin in patients receiving a VentriClear Catheter.	although there have been no reports of detected systemic levels of minocycline or rifampin in patients receiving a VentriClear Catheter. • [VentriClear catheters / The VentriClear II] are contraindicated for use in pregnant women.
Catheter	Material	Silicone	Silicone	Identical
	Size	9 Fr	9 Fr	Identical
	Length	33 cm	33 cm	Identical
	Sideports	32	16	32 (VentriClear), 16 (VentriClear II)
	End-hole	Closed	Closed	Identical
	Depth Marks	Yes	Yes	Identical
	Tip	Radiopaque	Radiopaque	Identical
	Antimicrobial Agents	Minocycline/Rifampin	Minocycline/Rifampin	Identical
Set Components		Pre-loaded stainless steel stylet/obturator, stainless steel tunneling trocar with proximal fittings, Luer Lock Plug, Female Luer Lock Adapter, Snap Fit Cap, and Silicone Winged Tie Down	Pre-loaded stainless steel stylet/obturator, stainless steel tunneling trocar with proximal fittings, Luer Lock Plug, Female Luer Lock Adapter, Snap Fit Cap, and Silicone Winged Tie Down	Identical
Packaging		Tyvek/polyester pouch	Tyvek/polyester pouch	Identical
Sterilization		EtO	EtO	Identical
Shelf Life		2 years	2 years	Identical



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Nonclinical Testing:

There were no device changes, so no additional testing was required to support the determination of substantial equivalence to the predicate devices.

Conclusion:

The subject devices are substantially equivalent to the predicate devices, the Spectrum[®] Ventricular Catheter (K011812) and the VentriClear[®] II Ventricular Drainage Catheter Set (K071640).