DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

August 31, 2017

Arkis BioSciences, Inc.
Mr. Joseph Howell
Quality and Regulatory Affairs Manager
1059 N. Cedar Bluff Road #157
Knoxville, Tennessee 37923

Re: K170599
Trade/Device Name: SureFlo EVD Catheter
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: August 1, 2017
Received: August 2, 2017

Dear Mr. Howell:

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 (DICE) 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 (DICE) 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,

William J. Heetderks -S
2017.08.31 13:28:40 -04'00'

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

Enclosure

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)*

K170599

Device Name

SureFlo EVD Catheter

Indications for Use *(Describe)*

The SureFlo EVD Catheter is indicated for temporary insertion into a ventricular cavity of the brain for external drainage of cerebrospinal fluid (CSF) in those patients with elevated intracranial pressure (ICP), intraventricular hemorrhage, or hydrocephalic shunt infections.

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

510(k) Number K170599

Arkis BioSciences Inc.
1059 North Cedar Bluff Rd.
Number 157
Knoxville, TN 37923
(844) 247-5383

Date Prepared August 29, 2017

Contact Joseph Howell
Quality and Regulatory Affairs Manager
(844) 247-5383 ext. 2

Trade Name SureFlo™ EVD Catheter

Common Name External Ventricular Drainage Catheter

Classification Class II

Regulation Number 21 CFR 882.5550

FDA Product Code JXG

Classification Name Shunt, Central Nervous System and Components

Predicate Device(s):
Primary Predicate: TraumaCath, Integra NeuroSiciences (K972994)
Predicate: Neurocath Ag, Vygon Neuro, (K081942)
Reference Device: NMI PICC III, Navilyst Medical (K121089)

Performance Standards: Performance standards for external monitoring and drainage systems have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act.

Device Description

The SureFlo EVD Catheter is a 3.3 mm diameter (10 Fr.), 35 cm long polyurethane catheter for diverting cerebrospinal fluid (CSF) from the ventricles of the brain through drainage holes near the catheter's bullet shaped tip. Similar to the predicate, the catheter is barium- sulfate- impregnated to provide radiopacity. Black stripes are located every 1 cm between 5 cm and 15 cm from the catheter tip to assist the surgeon in catheter placement. Double stripes and numerical markings are located at 10 cm and 15 cm. (All dimensions are nominal).

The SureFlo EVD Catheter is provided with a stainless steel Stylette, stainless steel Trocar, Barbed Luer Connecter, Male Luer Cap and silicone Suture Clip. The stainless-steel Stylet facilitates catheter placement for introduction of the catheter into the ventricle or other ventricular target site. A Trocar is supplied with the catheter to facilitate subcutaneous tunneling away from the burr hole. The external portion of the catheter may be secured to the scalp by the radiopaque Suture Clip. The Barbed Luer Connector supplied with each SureFlo EVD Catheter will connect the catheter to external drainage systems. The included Male Luer Cap may be used to close (cap) the barbed luer connector until the catheter is connected to a drainage or monitoring device.

The SureFlo EVD Catheter and its accessories are provided sterile.

The SureFlo EVD Catheter is constructed of a thermoplastic polyurethane (TPU) elastomer, just as the predicate device, Vygon Neurocath Ag (K081942). The SureFlo EVD Catheter polymer contains barium sulfate for radiopacity.

The SureFlo EVD Catheter additionally contains Endexo polymer; a polymer which is blended into the SureFlo EVD Catheter. The Endexo polymer is present throughout the polyurethane matrix including the bulk of the catheter body, and at any molded / extruded surfaces. The same Endexo polymer technology is used in several class II medical devices, including the cited reference device, Navilyst Medical NMI PICC III (K121089), Navilyst Medical Bioflo Midline Catheter (K150407), and the Navilyst Medical NMI Dialysis Catheter (K131260). Additionally, the same Endexo formulation is used in the cited reference device, Navilyst Medical NMI PICC III (K121089).

The Endexo polymer in polyurethane has been shown to be effective in reducing platelet adhesion in-vitro and thrombus accumulation in vitro [1, 2], in vivo [1, 2], and reducing the clinical incidence of thrombus formation as reported in medical literature [3, 4, 5, 6].
Please note:

- In vitro evaluations and in vivo animal evaluations do not necessarily predict the clinical performance of the SureFlo EVD Catheter with respect to thrombus formation.
- The incidence of thrombus formation on polyurethane containing Endexo polymer in other medical devices and/or tissues systems does not necessarily predict the clinical performance of the SureFlo EVD Catheter for the intended use of CSF external drainage and monitoring.

REFERENCES:
[1] R. Lareau and F. Facchini, “A New Option for Short- or Long-Term Peripheral Access to the Central Venous System: A product technology overview of the BioFlo PICC with Endexo Technology, with and without PASV Valve Technology,” AngioDynamics, Inc., 2014.

[2] See test reports in the FDA cleared 510(k) application K121089 “Navilyst Medical NMI PICC III”.

[3] L. Sustar and M. Kertesz, "Anti-Thrombogenic Non-Eluting Polyurethane PICC vs. Conventional Polyurethane PICC Upper Extremity DVT Rate," in Association for Vascular Access 2013 Annual Scientific Meeting, Nashville, TN, 2013.

[4] J. Webb and S. Rineair, "Changing the Outcome for the Pediatric Peripherally Inserted Central Catheter Patient: Decreasing Occlusion Complications with the Implementation of the BioFlo Peripherally Inserted Central Catheter with Pressure Activated Safety Valve," in Association For Vascular Access 2013 Annual Scientific Meeting, Nashville, TN, 2013.

[5] H. Polenakovik, A. Patton and J. Jenkins, "Incidence Rates of Symptomatic Peripherally Inserted Central Catheter - Related Deep Vein Thrombosis in Hospitalized Non-trauma Patients – Comparison Study of Two PICC Designs," in Association For Vascular Access 2014 Annual Scientific Meeting, National Harbor, MD, 2014.

[6] L. Crites, "Reducing Catheter-Related Complications with New Anti-Thrombogenic PICC," Journal of the Association for Vascular Acess, vol. 30, no. 4, p. 256, 2015.

Indication for Use

The SureFlo EVD Catheter is indicated for temporary insertion into a ventricular cavity of the brain for external drainage of cerebrospinal fluid (CSF) in those patients with elevated intracranial pressure (ICP), intraventricular hemorrhage, or hydrocephalic shunt infections.

Comparison of Technological Characteristics with the Predicate Devices

At a high level, the SureFlo EVD Catheter (subject device), the primary predicate (Integra TraumaCath (K972994)), and the predicate device (Neurocath Ag Vygon (K081942)), are based on the following same technological elements:

- The subject device, primary predicate, and predicate device utilize the same mode of action.
- Dimensions between the subject device and the primary predicate device are identical.
- The number of flow holes between the subject device, primary predicate, and predicate device are the same.
- The catheter from the subject device, primary predicate device, and predicate device have depth markings applied to the exterior of the catheter.
- The subject device and the primary predicate utilize the same type and number of accessories.

The following technological differences exist between the subject device (Arkis SureFlo EVD Catheter), primary predicate (Integra TraumaCath (K972994)), and the predicate (Vygon Neurocath Ag (K081942)):

- The catheter material utilized in the subject device (SureFlo EVD Catheter), the primary predicate Integra TraumaCath (K972994), and the predicate device Vygon Neurocath Ag (K081942) are different. Consequently, the SureFlo EVD Catheter was evaluated for biocompatibility and bench-top performance and was found to be biocompatible for its intended use.

Table 1 contains a summary of technological similarities and differences for the SureFlo EVD Catheter, the primary predicate, and the predicate device.

Table 1: Comparison and Differences of Technological Characteristics.

Technological Characteristic	**SureFlo EVD Catheter Set Arkis Biosciences (Subject Device)**	**TraumaCath Integra NeuroSicences (K972994) Primary Predicate Device**	**Neurocath Ag Vygon 8835.239 (K081942) Predicate Device**
Catheter Dimensions			
Outer Diameter:	3.3 mm	3.3 mm	2.9 mm
Inner Diameter:	1.9 mm	1.9 mm	1.8 mm
Length:	35 cm	35 cm	32 cm
Flow Holes	16	16	16
Set Contents	One Each of the Following Catheter Stainless Steel Stylette Stainless Steel Trocar Barbed Luer Connector Male Luer Cap Silicone Suture Clip	One Each of the Following Catheter Stainless Steel Stylette Stainless Steel Trocar Barbed Luer Connector Male Luer Cap Silicone Suture Collar	One Each of the Following Catheter Stainless Steel Stylette Stainless Steel Trocar Male Luer Connector Slitted Wing Compression Hub

Technological Characteristic	SureFlo EVD Catheter Set Arkis Biosciences (Subject Device)	TraumaCath Integra NeuroSicences (K972994) Primary Predicate Device	Neurocath Ag Vygon 8835.239 (K081942) Predicate Device
Catheter Markings (listed as distance from the tip)	Black stripes are located every cm between 5 cm and 15 cm from the catheter tip. Double stripes and numerical markings are located at 10 cm and 15 cm.	Markings every cm from 3 to 15 cm ± 1.5 mm with number located at odd markings, and dots located at even markings.	Markings at 3, 4, 5, 6, 7, 8, 9, 10, 15, and 20 cm. A specific marking is added 7.5 cm from the tip
Catheter Materials	Polyurethane with Barium Sulfate Endexo polymer Blue colorant	Barium Striped Silicone Tantalum impregnated tip	Polyurethane Silver ions (for radiopacity)

Bench testing of the Arkis SureFlo EVD Catheter per ISO 7197:2006 and ASTM F647-94(2014), and biocompatibility testing per ISO 10993-1:2009/(R)2013 demonstrate that the difference in material does not raise any new or different questions of safety or effectiveness compared to the primary predicate Integra TraumaCath (K972994).

Performance Data

Performance Testing - Bench

The SureFlo EVD Catheter was tested per the FDA- recognized consensus standards ISO 7197(2006) and ASTM F647-94(2014). The testing was performed to verify the performance specifications of the SureFlo EVD Catheter and to demonstrate equivalence in function to the predicate external ventricular drainage catheters.

The SureFlo EVD Catheter meets all of the performance specifications given in ISO 7197(2006) and ASTM F647-94(20014). Where no specific performance specification was given in the standards, the SureFlo EVD Catheter was found to have equivalent performance to the predicate ventricular drainage catheter to which it is being compared.

Table 2 summarizes the benchtop performance testing of the Arkis SureFlo EVD Catheter.

Performance Testing - Sterility

The SureFlo EVD Catheter is sterilized using ethylene oxide in per ISO 11135:2014. Sterilization validation demonstrated that the selected sterilization process achieves a sterility assurance level (SAL) of $<10^{-6}$. The ethylene oxide residuals on the device were within the limits specified in Section 4.3.3 of ISO 10993-7:2008 for prolonged contact devices. The bacterial endotoxin levels were quantified on sterilized devices per ANSI ST72:2011, and were less than the limits recommended by the FDA for devices in direct contact with CSF.

The SureFlo EVD Catheter meets the requirements for sterility given in the FDA Guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."

Table 3 summarizes the sterility testing of the Arkis SureFlo EVD Catheter.

Performance Testing - Shelf Life and Package Integrity

The product's shelf life was established through benchtop testing of real-time aged devices and package integrity testing of accelerated aged products. Bench top testing of aged

devices was performed per ISO 7197(2006) and ASTM F647-94(2014). The integrity of accelerated aged packages (ASTM F1980-16) was evaluated per ASTM D4169-16, ASTM F2096-11, F88/F88M-15, and ASTM F1608-16.

This testing demonstrated that aged SureFlo EVD Catheter devices and packaging have the same performance characteristics as new devices and packaging.

Table 4 summarizes the device performance testing and package integrity testing used to establish the SureFlo EVD Catheter's shelf life.

Performance Testing – Summary

The results of the performance testing (bench, sterility, shelf life and package integrity) demonstrates the SureFlo EVD Catheter is as safe, as effective, and performs as well or better than the primary predicate Integra TraumaCath (K972994) for its intended use.

Table 2: Bench Testing Summary.

Test Description	Test Summary	Results
Pressure and Flow Characteristics ISO 7197:2006 ASTM F647-94	Catheter + luer barb assemblies were tested at various flow rates and to characterization of the pressure and flow curve for the catheter and luer barb assembly.	**Pass:** The characterization of pressure and flow was successfully completed.
Resistance to Overpressure ISO 7197:2006	Catheter + luer barb assemblies were tested for significant differences in flow rates, pre-and-post-test, to being subjected to a pressure equivalent to a 1 m water column. Additionally, catheters were observed for any signs of damage or leakage.	**Pass:** There were no significant differences in flow rates and there was no evidence of damage or leakage on the tested samples.
Bursting Pressure ISO 7197:2006	Catheter + luer barb assemblies were tested to a pressure equivalent to a 2m water column, for a defined period of time and reviewed for signs of damage or leakage. Additionally, for a different defined time-period, flow rates were compared pre-and-post-test to ensure mean pressure at prescribed flow rates had not changed more than the allowed variance of the mean values.	**Pass:** There was no evidence of damage or leakage and the mean value flow rate did not change more than the allotted value pre-and-post-testing.
Resistance to Leakage ISO 7197:2006	An air pressure equivalent to a 1 m water column was applied to catheter + luer barb + male luer cap assemblies submerged in water for a defined period of time and observed for any signs of leakage.	**Pass:** Samples did not show any indication of leakage.
Durability ASTM F647-94	Catheter + luer barb assemblies were submerged in deaerated distilled water at 37C for 28 days, and water was circulated at a prescribed flow rate through catheter assemblies for a prescribed duration. At the end of the prescribed duration, the catheter assemblies were examined for damage. The pressure and flow characteristic were measured to ensure there was no significant difference between pre-submersion and post-submersion.	**Pass:** After submersion and circulation for 28 days, the samples showed no indication of damage and the post-submersion flow rates were not statistically different when compared to the flow rates of the samples pre-submersion.

Test Description	Test Summary	Results
Static Breaking Strength ASTM F647-94	Catheter + luer barb were loaded with an increasing longitudinal force until the catheter disassembled from the luer, or until the catheter or luer fractures.	**Pass:** The Arkis SureFlo EVD Catheter assemblies tested disassembled or failed at higher forces than the primary predicate assemblies tested for comparison.
Flexibility ASTM F647-94	Catheter + luer barb were wrapped around pins and a positive air pressure was applied to the inside of the catheter. The catheter was wrapped around decreasing pin diameters until the catheter became obstructed.	**Pass:** Arkis SureFlo EVD Catheter samples tested were obstructed when wrapped around a smaller diameter pin then the predicate device.
Dynamic Breaking Strength ISO 7197:2006	Catheter + luer barb assemblies were subjected to a dynamic longitudinal load (up to 5 N or 10% of elongation) for a prescribed maximum number of cycles or until failure occurs.	**Pass:** The samples tested met the prescribed maximum number of cycles without failure.
Radiopacity ISO 7197:2006 ASTM F647-94	X-ray catheter and suture clips alongside standardized control specimens of a specified thickness and specified alloy. Compare the pixel intensity of the catheter and suture clip to background and suture clip-to-background, at multiple locations. The test articles must be at least as radiopaque as the control specimens.	**Pass:** The test articles met or exceeded the radiopacity requirements as compared with the control specimens.

Table 3: Sterilization Testing Summary.

Test Description	Test Summary	Results
Ethylene Oxide Sterilization per ISO 11135:2014	The bioburden of non-sterilized packaged catheters was quantified. Fractional ethylene oxide cycles were used to determine the relative resistance of the device bioburden compared to a standard biological indicator. The packaged catheters were then exposed to a full ethylene oxide cycle to achieve an SAL of $<10^{-6}$.	**Pass:** The devices were sterile with an SAL $<10^{-6}$.
Ethylene Oxide Residuals per ISO 10993-7:2008	The ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals on the catheters were quantified and compared to the limits specified in Section 4.3.3 of ISO 10993-7:2008 for prolonged contact devices.	**Pass:** The EO and ECH levels were less than the established limits for prolonged contact devices.
Bacterial Endotoxin (Limulus Amebocyte Lysate (LAL) Assay) ANSI ST72:2011	Bacterial endotoxin levels were quantified on packaged devices prior to sterilization compared to the limit established by the FDA for devices in direct contact with CSF. The LAL test method was validated by inhibition and enhancement testing.	**Pass:** The bacterial endotoxin levels were less than the established limit. Non-pyrogenic

Table 4: Shelf Life: device performance and package integrity testing summary.

Test Description	Test Summary	Results
Resistance to Leakage ISO 7197:2006	Real-time aged devices were tested. An air pressure equivalent to a 1 m water column was applied to catheter + luer barb + male luer cap assemblies submerged in water for a defined period of time and observed for any signs of leakage.	**Pass:** Samples did not show any indication of leakage. No change from non-aged samples.

Test Description	Test Summary	Results
Dynamic Breaking Strength ISO 7197:2006	Real-time aged devices were tested. Catheter + luer barb assemblies were subjected to a dynamic longitudinal load (up to 5 N or 10% of elongation) for a prescribed maximum number of cycles or until failure occurs.	**Pass:** The samples tested met the prescribed maximum number of cycles without failure. No change from non-aged samples.
Static Breaking Strength ASTM F647-94	Real-time aged devices were tested. Catheter + luer barb were loaded with an increasing longitudinal force until the catheter disassembled from the luer, or until the catheter or luer fractures.	**Pass:** The Arkis SureFlo EVD Catheter assemblies tested disassembled or failed at higher forces than the primary predicate assemblies tested for comparison. No change from non-aged samples.
Flexibility ASTM F647-94	Real-time aged devices were tested. Catheter + luer barb were wrapped around pins and a positive air pressure was applied to the inside of the catheter. The catheter was wrapped around decreasing pin diameters until the catheter became obstructed.	**Pass:** Arkis SureFlo EVD Catheter samples tested were obstructed when wrapped around a smaller diameter pin than the predicate device. No change from non-aged samples.
Accelerated Aging ASTM F1980-16	Accelerated aging conducted prior to distribution and package integrity testing.	**Pass:** Accelerated aging completed at specified parameters.
Distribution Simulation ASTM D4169-16	Testing performed on accelerated aged products. Distribution simulation of shipper boxes containing individual device packages per ASTM D4169 distribution cycle 13 with Schedule I omitted and Schedule J not performed.	**Pass:** Shipping unit remained intact with no rips, punctures, tears, or crushing. Shipping unit met the same specifications as non-aged samples.
Bubble Emission Test ASTM F2096-11	Testing performed on accelerated aged and distributed products. Detects leaks in sterile barrier pouches through the emission of bubbles when the pouches are inflated and placed underwater.	**Pass:** No bubbles were emitted from any of the tested packaging. Meets same specifications as non-aged/distributed samples.
Pouch Seal Test ASTM F88/F88M-15	Testing performed on accelerated aged and distributed products. Determines the strength sterile barrier (pouch) seal by mechanically pulling on sections of the pouch seal.	**Pass:** The sterile barrier seal strength exceeded the minimum specification for non-aged/distributed samples.
Microbial Ranking ASTM F1608-16	Testing performed on accelerated aged and distributed products. Quantifies the log reduction value in number of aerosolized bacterial spores passing through porous sterile barrier materials.	**Pass:** The porous sterile barrier material met the same performance specification as non-aged/distributed sterile barrier.

Biocompatability

The Arkis SureFlo EVD Catheter was evaluated following ISO 10993-1:2009/(R)2013, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" per the FDA guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'"

The biocompatibility assessments demonstrated that the SureFlo EVD Catheter and the accessories included in the set are biocompatible for their intended use.

The biocompatibility testing is summarized in Table 5.

Table 5: Biocompatibility Testing Summary

Test	Results	Conclusions
Cytotoxicity ISO 10993-5:2009	The viability percentage of the cells exposed to the 100% (neat) test article extract was within acceptable limits.	**Pass:** Non-cytotoxic
Sensitization ISO 10993-10:2010	Extracts of the test articles elicited no reaction at the test challenge (0% sensitization).	**Pass:** Non-sensitizing
Irritation or Intracutaneous Reactivity ISO 10993-10:2010	Extracts of the test articles were evaluated for their potential to produce irritation. The test articles did not show a significantly greater biological reaction than the sites injected with the control article.	**Pass:** Non-irritating
Acute Systemic Toxicity ISO 10993-11:2006	Extracts of the test articles did not induce a significantly greater biological reaction than that of the control extracts.	**Pass:** No Acute System Toxicity
Material-Mediated Pyrogenicity ISO 10993-11:2006	Extracts of the test articles did not produce a pyrogenic response when tested.	**Pass:** Non-pyrogenic
Genotoxicity (Ames Assay) ISO 10993-3:2014	Extracts of the test articles did not induce a biologically significant increase in the number of revertant (mutated) bacterial colonies.	**Pass:** Non-mutagenic
Genotoxicity (Micronucleus Assay) ISO 10993-3:2014	Extracts of the test articles did not induce a statistically significant increase in the percentage of reticulocytes containing micronuclei and test articles did not induce a clastogenic effect in maturing erythrocytes.	**Pass:** Non-clastogenic
Genotoxicity (Mutagenesis Assay) ISO 10993-3:2014	The increased mutant frequency (IMF) of cells exposed to test article extracts was less than the test criteria for the main and confirmation assays for all concentrations tested.	**Pass:** Non-mutagenic
Hemocompatibility (Complement Activation) ISO 10993-4:2002	The concentrations of C3A and SC5B-9 in the plasma exposed to the test article was not significantly increased from the concentrations in the negative and untreated controls.	**Pass:** Did not activate complement system in plasma
Hemocompatibility (Hemolysis) ISO 10993-4:2002 ASTM F756-13	The test article exhibited a hemolysis index of that was not significantly above the negative control for the direct and indirect contact methods.	**Pass:** Non-hemolytic
Hemocompatibility (In Vitro) ISO 10993-4:2002	The concentration of White Blood Cells (WBC) and Platelets (Plt) exposed to the test article was not significantly decreased in comparison to the negative control article and was not statistically significantly decreased in comparison to the untreated control.	**Pass:** No effect on selected hematological parameters
Hemocompatibility (Unactivated Partial Thromboplastin Time) ISO 10993-4:2002	The Unactivated Partial Thromboplastin Time (UPTT) was not significantly decreased in comparison to the negative and untreated controls.	**Pass:** No effect on coagulation
Subacute Toxicity via Brain and Subcutaneous Implantation ISO 10993-6:2007 ISO 10993-11:2006	For all parameters tested, animals implanted with the test article did not demonstrate any differences considered attributable to the test article compared to those animals implanted with the control article.	**Pass:** No local or systemic sign of toxicity

Conclusion The SureFlo EVD Catheter is substantially equivalent to the primary predicate Integra TraumaCath (K972994), per the criteria given in FDA Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]".

Note: Trademarks cited for predicates are owned by the respective companies.