January 5, 2026

Kaneka Americas Holding, Inc.
% Darci Diage
Quality and Regulatory Consultant
MedEdge
635 Hibiscus Street, #2101
West Palm, Florida 33401

Re: K251668
Trade/Device Name: SurfRider 13 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, KRA
Dated: December 4, 2025
Received: December 4, 2025

Dear Darci Diage:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251668

Device Name
SurfRider 13 Microcatheter

Indications for Use *(Describe)*
The SurfRider 13 Microcatheter is intended for the introduction of interventional devices, such as embolic coils, or diagnostic agents into the neurovasculature.

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.

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510(k) Summary

Date of preparation:	December 30, 2025
Submitter:	Kaneka Americas Holding, Inc. 7979 Gateway Blvd., Suite 220 Newark, CA 94560
Contact Person:	Darci Diage MedEdge 635 Hibiscus St, #2101 West Palm, FL 33401 Phone: (707) 953-2615 e-mail: darci@tpconsulting.net
Trade Name:	SurfRider 13 Microcatheter
Common Name:	Percutaneous catheter
Classification:	Class II
Product Code:	QJP, KRA
Regulation:	870.1250 (Percutaneous Catheter), 870.1210 (Continuous Flush Catheter)
Predicate Device(s):	Phenom™ Catheters K210230
Reference Device(s):	Marathon™ Flow Directed Micro Catheter K202318
Device Description:	The SurfRider 13 Microcatheter is a single-lumen microcatheter with a gradual stiffness change from tip to proximal end, reinforced with a metal braid to facilitate delivery to distal vessels and to serve as a delivery path of contrast media, embolic agents and coils. The distal end has two radiopaque markers to facilitate fluoroscopic visualization, and two types of tips: a straight tip and a pre-shaped tip. The proximal end of the Microcatheter incorporates a standard luer adaptor to facilitate the attachment of accessories. The outer surface of the Microcatheter has a hydrophilic coating to increase lubricity. The Microcatheter is designed to be introduced over a steerable guidewire into the vasculature.
Indication for Use:	The SurfRider 13 Microcatheter is intended for the introduction of interventional devices, such as embolic coils, or diagnostic agents into the neurovasculature.

Comparison of technological characteristics with the predicate

The subject device has the same principle of operation and similar technological characteristics as the predicate device Phenom™ Catheters (K210230 cleared on February 25, 2021) and the reference device Marathon™ Flow Directed Micro Catheter (K202318 cleared on September 14, 2020).

A tabular comparison of the intended use and technological characteristics between the subject, predicate and reference devices is provided below:

	SurfRider 13 Microcatheter (Subject Device)	**Phenom™ Catheters (Predicate Device)**	**Marathon™ Flow Directed Micro Catheter (Reference Device)**
510(k) Number	K251668	K210230	K202318
Manufacturer	Kaneka Americas Holding, Inc.	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Classification	Class II	Class II	Class II
Product Code(s)	QJP, KRA	DQY, QJP, KRA	KRA, QJP
Regulation	870.1250 870.1210	870.1250 870.1210	870.1210 870.1250
Medical Specialty	Cardiovascular	Cardiovascular	Cardiovascular
Indications for Use	The SurfRider 13 Microcatheter is intended for the introduction of interventional devices, such as embolic coils, or diagnostic agents into the neurovasculature.	Phenom™ Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.	The Marathon™ Flow Directed Micro Catheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.

	SurfRider 13 Microcatheter (Subject Device)	Phenom™ Catheters (Predicate Device)	Marathon™ Flow Directed Micro Catheter (Reference Device)
Proximal/Distal Outer Diameter (OD)	Proximal: 0.037” Distal: 0.022”	Proximal: 0.029”-0.061” Distal: 0.024” – 0.055”	Proximal: 0.040” Distal: 0.020”
Distal Inner Diameter (ID) at Tip	0.013”	0.017”-0.0445”	0.013”
Min. Guiding Catheter ID	≥ 0.070”	≥ 0.035” – 0.070”	≥ 0.053”
Max. Guidewire OD	≤ 0.010”	≤ 0.014” – 0.041”	≤ 0.010”
Effective Length	165 cm	75-170 cm	165 cm
Distal Segment Length	5 cm	6 – 20 cm	25 cm
No. of Lumens	Single lumen	Single lumen	Single lumen
Shaft	Progressively softer from proximal end to distal tip	Progressively softer from proximal end to distal tip	Semi-rigid proximal shaft and a highly flexible distal shaft
Shaft Materials	PTFE and Pebax	PTFE and Pebax	PTFE, Grilamid and Pebax
Shaft Reinforcement	Metallic (Stainless Steel) reinforced	Metallic (Stainless Steel) reinforced	Stainless Steel helical coil
Inner Liner	PTFE liner	PTFE liner	PTFE liner
Marker Band	Platinum-Iridium Alloy	Radiopaque marker band	Platinum-Iridium Alloy
Tip Markers	2	1-2	1
Tip Shaping	Pre-shaped and steam shapeable straight tips	Pre-shaped and steam shapeable straight tips	Steam shapeable straight tip
Coating	Hydrophilic coating	Hydrophilic coating	Proprietary Hyaluronic acid, acrylic resin binder
Shaping Mandrel	Yes	Yes	Yes
Introducer Sheath	Yes	Yes	No
Sterilization Method	Ethylene Oxide (EO)	EO	EO
Minimum SAL	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}
Method of Supply	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use
Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1
Shelf-Life	36 months	12 months	12 months

Performance bench testing

Non-clinical bench testing was performed to evaluate the SurfRider 13 Microcatheter and to support substantial equivalence. The following testing/assessments were performed:

Test	Test method summary	Results/conclusion
Visual appearance	Catheter surface was checked for cleanliness and absence of defects.	All samples met the acceptance criteria.
Dimensions	Catheter dimensions were measured to confirm they meet design specifications.	All samples met the acceptance criteria.
Radiopacity	The catheter was evaluated for visibility under X-ray imaging.	All samples met the acceptance criteria.
Simulated use	The catheter was used in a simulated anatomical model to assess overall performance and compatibility with ancillary devices.	All samples met the acceptance criteria.
Compatibility with liquid embolic materials	Compatibility with liquid embolic materials was evaluated.	All samples met the acceptance criteria.
Flow rate	Flow rate through the catheter was measured.	All samples met the acceptance criteria.
Liquid leakage	The catheter was pressurized with liquid and checked for leaks.	All samples met the acceptance criteria.
Air leakage	Vacuum was applied and the hub was examined for leaks.	All samples met the acceptance criteria.
Static burst pressure	The catheter was pressurized until failure to assess burst pressure.	All samples met the acceptance criteria.
Peak tensile force	Tensile force was applied to every joint to assess mechanical strength.	All samples met the acceptance criteria.
Tip stiffness	Flexibility of the catheter tip was measured.	All samples met the acceptance criteria.
Steam shape retention	Shape retention after steam shaping was measured.	All samples met the acceptance criteria.
Kink resistance	The catheter was wrapped around mandrels of various sizes to assess resistance to kinking.	All samples met the acceptance criteria.
Torque resistance	The catheter was rotated in a simulated anatomical model to assess resistance to torsional stress.	All samples met the acceptance criteria.
Dynamic burst pressure	Dynamic resistance to liquid injection pressure was measured.	All samples met the acceptance criteria.
Corrosion resistance	Evaluated per ISO 10555-1.	All samples met the acceptance criteria.
Coil deliverability	Performance during delivery of embolization coils through the catheter was assessed in a simulated anatomical model.	All samples met the acceptance criteria.
Stability while coiling	Catheter stability during coil embolization was assessed in a simulated anatomical model.	All samples met the acceptance criteria.
Coil delivery force	Coil delivery force was measured in a simulated anatomical model.	All samples met the acceptance criteria.
Hub	The hub was tested for dimensions, leakage, mechanical integrity and compatibility.	All samples met the acceptance criteria.
Coating integrity/particulate	The catheter was tracked in a simulated anatomical model to assess coating integrity and particulate release.	All samples met the acceptance criteria.
Coating lubricity	Pinch friction forces were measured.	All samples met the acceptance criteria.

Non-clinical bench testing demonstrated that the SurfRider 13 Microcatheter met all pre-established acceptance criteria, functions as intended, and performs similar to the predicate device and the reference device.

Biocompatibility

The biocompatibility evaluation for the SurfRider 13 Microcatheter was conducted in accordance with the FDA guidance, "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"," and International Standard ISO 10993 series. Per ISO 10993-1, the SurfRider 13 Microcatheter was categorized as an externally communicating device with circulating blood contact for a limited duration of contact (≤ 24 hours). The biocompatibility testing included the following tests:

Test	Test summary	Conclusion
Acute systemic toxicity Systemic injection ISO 10993-11	Determine the potential toxic effects of the test article extract resulting from a single-dose systemic injection of polar and non-polar extracts in mice.	Non-toxic
Cytotoxicity MEM elution method ISO 10993-5	Determine the potential cytotoxicity of a mammalian cell culture (L929) in response to the test article extract.	Non-cytotoxic
Intracutaneous irritation Intracutaneous injection ISO 10993-23	Determine the potential irritation effect of the test article extract resulting from intracutaneous injection of polar and non-polar extracts in rabbits.	Non-irritant
Material mediated pyrogenicity Rabbit pyrogen study ISO 10993-11	Determine the potential presence of material-mediated pyrogen.	Non-pyrogenic
Sensitization Maximization test ISO 10993-10	Determine the potential delayed dermal contact sensitization effect of the test article extract resulting from repeated injection of polar and non-polar extracts in guinea pig.	Non-sensitizing
Hemocompatibility Hemolysis (extract and direct contact) ISO 10993-4	Determine the potential hemolytic effect of the test article resulting from direct and indirect (extract) contact.	Non-hemolytic
Hemocompatibility Complement activation (SC5b-9) ISO 10993-4	Determine the potential activation of the SC5b-9 complement system for the test article and the comparison article.	Non-activator
Hemocompatibility Partial thromboplastin time assay ISO 10993-4	Determine the potential activation of the human blood coagulation pathway for the test article and the comparison article.	Non-activator
Hemocompatibility Platelet and leukocyte counts ISO 10993-4	Determine the potential effect for platelet and leukocyte ratios in human whole blood for the test article and the comparison article.	No effect
Hemocompatibility In vitro blood loop assay ISO 10993-4	Determine the thrombogenicity of sheep whole blood for the test article and the comparison article.	Thromboresistant

In addition to the performance testing and biocompatibility testing, compatibility with liquid embolic materials was further assessed using a paper-based risk assessment.

Sterility

The SurfRider 13 Microcatheter sterilization process using ethylene oxide (EO) has been validated in accordance with ISO 11135-1:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and ethylene chlorohydrin (ECH) residuals were below limits specified in ISO 10993-7:2008. Bacterial endotoxin levels were below the level of 2.15 endotoxin units (EU)/device.

Shelf-life

Both baseline and accelerated shelf-life testing were conducted. The results demonstrated that the SurfRider 13 Microcatheter has three-year shelf life.

Animal testing

No animal testing was conducted. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Clinical testing

No clinical testing was conducted. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Conclusions

The SurfRider 13 Microcatheter's intended use, indications for use, materials, and fundamental scientific technology are similar to the predicate device. The differences between the subject device and the predicate device do not raise new questions of safety and effectiveness. Bench, biocompatibility, and shelf-life testing demonstrate that the subject device performs as intended and is substantially equivalent to the predicate device.