April 25, 2020

Kaneka Pharma America LLC
℅ Takeaki Miyata
Manager, Regulatory Affairs & Quality Assurance Team
Kaneka Corporation
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Japan

Re: K192068
Trade/Device Name: i-ED COIL System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: March 25, 2020
Received: March 26, 2020

Dear Takeaki Miyata:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Xiaolin Zheng, Ph.D., M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192068

Device Name
i-ED COIL System

Indications for Use *(Describe)*
The i-ED COIL System (i-ED COIL and EDG v4) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The i-ED COIL System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

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

i-ED COIL System

510(k) Submitter

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Date Prepared: April 25, 2020

Subject Device Name:

Trade Name	i-ED COIL System
Common or usual name	Neurovascular Embolization Device and Vascular Embolization Device
Classification name	Neurovascular Embolization Device [21 CFR 882.5950; product code HCG] and Vascular Embolization Device [21 CFR 870.3300; product code KRD]
Class	II
Classification Panel	Neurology (84) and Cardiovascular (74)

Predicate Devices:

- Primary predicate device: Target Detachable Coils / InZone Detachment System (or Target Coils and InZone System) [K161429 / K160096 (Stryker Neurovascular)]
- MicroPlex Coil System [K162999 (MicroVention, Inc.)]
- Barricade Embolization Coil System (or Barricade Coil System) [K151760 (Blockade Medical)]

These predicate devices have not been subject to a design-related recall.

Device Description:

i-ED COIL System is a neurovascular and vascular embolization device, which consists of two component devices, i-ED COIL Detachable Coil (hereafter i-ED COIL) and ELECTRO DETACH GENERATOR v4 Detachment System (hereafter EDG v4).

The i-ED COIL is composed of a detach coil and a sheath adapter. Furthermore, the detach coil consists of a platinum coil (embolization material), to be placed at the site of vascular diseases, a pusher (delivery wire) to guide the platinum coil to the site and a PVA (polyvinyl alcohol) rod that connects the platinum coil and the pusher. The sheath adapter consists of a PP (polypropylene) sheath and an adapter. The i-ED COIL is designed for use with the EDG v4.

The EDG v4 consists of a power source and connection cables attached with clips. EDG v4 is a medical electrical equipment to be used to detach the implantable platinum coil from the delivery wire of the i-ED COIL. It is intended for use in multiple coil detachments performed during a single procedure.

The i-ED COIL and EDG v4 are provided sterile (EtO), and separately packaged and distributed in the U.S.

Indications for Use

The i-ED COIL System (i-ED COIL and EDG v4) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

The i-ED COIL System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

Comparison of Indications for Use to Predicate Devices

The i-ED COIL System has the same intended use (vascular and neurovascular embolization and permanent occlusion of blood flow) as the Target Coils and InZone System, MicroPlex Coil System and Barricade Coil System. The indications for use of the i-ED COIL System is identical to those of the MicroPlex Coil System and the Barricade Coil System, and similar to that of the Target Coils and InZone System.

Comparison of Technological Characteristics to Predicate Device

Catheter-based vascular and neurovascular intervention is the technological principle for both i-ED COIL System and the predicate devices. The vascular and neurovascular embolization coil devices including the i-ED COIL System and the predicate devices consist of a coil (embolization material) and a delivery wire and an instrument for detachment of a coil (detachment system device).

Comparison table of the technological characteristics to the primary predicate device is provided in Table 1 below:

Table 1 Comparison table about technological characteristics

Characteristics	Primary Predicate Device	Subject Device	Identicalness / similarity, or difference
	Target Coils and InZone System) [K161429 / K160096 (Stryker Neurovascular)]	i-ED COIL System (Kaneka Corporation)	
General Information			
Intended use	Vascular and neurovascular embolization and permanent occlusion of blood flow.	Vascular and neurovascular embolization and permanent occlusion of blood flow.	Identical
Configuration of an embolization coil device	The Target Coils consists of an embolization coil implant comprised of platinum-tungsten alloy, affixed to a delivery wire with an introducer sheath to	The i-ED COIL consists of an embolization coil implant comprised of platinum-tungsten alloy, affixed to a pusher (delivery wire) with a sheath	Similar

Characteristics	Primary Predicate Device Target Coils and InZone System) [K161429 / K160096 (Stryker Neurovascular)]	Subject Device i-ED COIL System (Kaneka Corporation)	Identicalness / similarity, or difference
	facilitate insertion into the hub of a microcatheter.	adapter to facilitate insertion into the hub of a microcatheter.	
Usage environments	Hospital, interventional neuroradiology sites	Hospital, interventional neuroradiology sites	Identical
Dimension/Shepe of Coil			
Primary coil outer diameter (mm)	0.25 to 0.43	• Helical: 0.25 to 0.43 • Complex: 0.25 to 0.35	Similar
Secondary coil outer diameter (mm)	1.0 to 24.0	• Helical: 1.5 to 24.0 • Complex: 1.0 to 16.0	Similar
Primary coil length (mm)	• Helical: 10 to 500 • Complex: 11 to 500	10 to 500	Similar
Deployed coil shape	Helical, Complex (360 shape, 3D)	Helical, Complex	Similar
Pusher length (mm)	1850	1870	Similar
Pusher outer diameter (grip part; mm)	0.34	0.335	Similar
Dimension of Detachment device			
Dimension (mm)	140 × 58 × 28	125 × 55 × 25	Similar
Material of Coil			
Coil	Platinum-tungsten alloy	Platinum-tungsten alloy	Identical
Inner line (stretch resistance)	Polypropylene suture (two lines)	Polypropylene internal line (two lines)	Identical
Pusher (main or core wire component)	Stainless steel	Stainless steel	Identical
Sheath	High density polyethylene with pigment	Polypropylene	Similar as thermoplastic resin
Specification of Detachment Device			
Coil detachment principle	Electrolytic dissolution of stainless steel	Thermal fusing of PVA rod	Different
Circuit system	• Bi-polar type (for Target) • Mono-polar type (for GDC and Matrix)	Mono-polar type	Similar to for detachment for GDC and Matrix
Power source	Two AAAA (1.5 V) batteries	Three AA(1.5V) alkaline batteries	Similar
Output current/voltage	Direct current (DC) up to 2.4 mA/ Volage up to 28 VDC	Alternate current (AC) up to 61.0 mA/ Voltage up to 22.5 V	Different
Detachments per unit	20	30 (based on the verification test result)	Similar
Other Characteristics			
Radiopaque marker of pusher	Yes	Yes (Platinum coil part of pusher)	Similar

Characteristics	Primary Predicate Device	Subject Device	Identicalness / similarity, or difference
	Target Coils and InZone System) [K161429 / K160096 (Stryker Neurovascular)]	i-ED COIL System (Kaneka Corporation)	
Concomitantly used devices	Microcatheter, guiding catheter, rotating hemostatic valve (RHV)	Microcatheter, guiding catheter, rotating hemostatic valve (RHV)	Identical
Compatible microcatheter of coil (inner diameter: mm)	0.41 to 0.48	0.33 to 0.53 (depending on dimensional specification of a platinum coil)	i-ED COIL has broder compatibility with microcather
MRI compatibility of coil (stated in the IFU/DFU)	MR conditional	MR conditional	Similar (detailed conditions are different)
Sterilization method	EtO	EtO	Identical

Performance Testing

To demonstrate substantial equivalence of i-ED COIL System to the predicate devices, the technological characteristics and performance criteria were evaluated in reference to the bench testing recommendations outlined in the FDA Guidance Document "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices" (dated December 29, 2004). *In vitro* tests in Table 2 below were performed on the subject device:

Table 2 Summary of performance testing

Test	Test Method Summary	Results
Appearance test on i-ED COIL	The purpose was to demonstrate that visual appearance of i-ED COIL meets pre-specified acceptance criteria and could be considered to be clinically usable. Visual inspection using a microscope was conducted on the detach coil and the sheath adaptor. In addition, the position markers was visually checked.	All samples had no visual abnormalities at all and passed the acceptance criteria.
Dimensional verification on i-ED COIL	The purpose was to demonstrate that dimensional values of i-ED COIL samples meet pre-specified acceptance criteria and the i-ED COIL samples are dimensionally designed as intended. Dimensions of the samples were measured with instruments (gauge, caliper, and scale).	All samples were confirmed to meet all acceptance criteria based on the dimensional specification.
Strength test on i-ED COIL	The purpose was to demonstrate that physical strength of i-ED COIL meet pre-specified acceptance criteria, and could withstand forces that the i-ED COIL may encounter in clinical usage. After swelling the PVA rod, inner line strength, product strengths, coil strength and pusher strength were measured by a tensile tester.	All samples without deviation passed each acceptance criterion. It was demonstrated that i-ED COIL has necessary strength for clinical usage.
Delivery performance test on i-ED COIL	The purpose was to demonstrate that delivery performance of i-ED COIL is at least equivalent to the control device that is legally distributed in the U.S. A test sample was inserted into the microcatheter in a simulated ICA circuit. Consequently, the test sample was	All samples met the acceptance criteria about maximum load based on the result of the control device.

Test	Test Method Summary	Results
	moved by a linear actuator. Each maximum load in five strokes (retracting and advancing) was measured by a force gauge to calculate its mean value.	
Detachment performance test on i-ED COIL System	The purpose was to demonstrate that i-ED COIL could be detachable with the EDG v4 within pre-specified time, and the combination of i-ED COIL and the EDG v4 is a reliable detachment mechanism for the clinical usage. According to the IFU, after the PVA rod of the detach coil was swelled, the detach coil was advanced through the sheath adapter. The detachment part of the sample was soaked in heparinized saline at 35°C in the beaker. The tester pressed the detach button of the EDG v4, and confirmed that the platinum coil could be successfully detached from the pusher within pre-specified time.	All test samples could be detached within the pre-specified time and met the acceptance criteria.
Detachment durability test on EDG v4	In order to demonstrate the detachment reliability of i-ED COIL System and durability of the EDG v4, it was measured whether sufficient power for the detachment of i-ED COIL was output from the EDG v4 samples during 30 times detachment operations using the digital power meter and non-inductive variable resistor.	Since the outputs from all EDG v4 samples during 30 times detachment procedures were stable, the acceptance criteria was met.
Corrosion resistance test on i-ED COIL	The purpose was to demonstrate that the i-ED COIL does not show sign of corrosions in the intended clinical use. In reference to ISO 11070: 2014, test procedures were carried out. The tester confirmed whether there was sign of corrosion in metal section of sample using a digital microscope.	In all test samples, there was no sign of corrosion. Therefore, the result met the acceptance criterion.
Particulate evaluation on i-ED COIL	The purpose was to demonstrate that the quantity and size of particulates generated during operation of i-ED COIL System are equivalent or less than particulates generated from the control device that is distributed in the U.S. The simulated use test model incorporated with the tortuous part was used for the evaluation. After 20 cycles of retraction and advancement of a test sample were repeated in the model, the platinum coil was detached with the EDG v4. The test sample solution and the baseline sample solution were analysed using the light obscuration tester.	The particulates generated from i-ED COIL were equivalent or less than the control device. Therefore, the result met the acceptance criterion.
Simulated use evaluation on i-ED COIL System	In order to simulate actual clinical environment, the vessel model with aneurysms, the biplane imaging system and simulated worst neurovascular system, guiding catheter, microcatheters, etc. were used in this test. Physicians who participated in this study, semi-quantitatively evaluated trackability and delivery performance in microcatheter, coil positioning performance, repositioning performance (repeat delivery), framing, filling and finishing performance, and detachment performance of i-ED COIL System.	Considering the test results, the i-ED COIL System was judged to be able to use without problems even in the very tortuous vasculature considered to be the worst case.
Usability evaluation on i-ED COIL System	The purpose was to evaluate the usability of i-ED COIL System by physician trained for neuro-interventional procedures. Prior to the testing, the physicians were briefed on the device operation, testing procedures, and were provided i-ED COIL and EDG v4 IFUs. The physicians semi-quantitatively	In all of stages, all of physicians scored the usability as equal to or greater than the acceptance criterion. Therefore, it was concluded that i-ED

Test	Test Method Summary	Results
	scored each stage (from the preparation of i-ED COIL and EDG v4 to the detachment of the platinum coil).	COIL System had adequate usability.
MRI Compatibility tests on i-ED COIL	In reference to related FDA Guidance 'Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment' and related ASTM F2052-15, ASTM F2213-06, ASTM F2182-11a, and ASTM F2119-07, effects of dispalacement force, torque, heating by RF fields, image artifact of MR imaging on implanted i-ED COIL were evaluated to establish safety and compatibility of i-ED COIL in the MR environment.	It was concluded that i-ED COIL was MR conditional as same as the predicate devices. The MR compatibility information was reflected appropriately in the labeling.
MRA Artifact on i-ED COIL	According to ASTM F2119-07, image artifact of i-ED COIL in MR Angiography was measured.	The worst-case image artifact by i-ED COIL was considered as minimal as with the predicate device.
Shelf Life testing on i-ED COIL	In order to establish shelf life of i-ED COIL, aging test was conducted on samples that underwent simulated transportation (according to ISO 4180) and accelerated-aged storage equivalent to three years real time storage. The test items were same as above-mentioned performance testing except for the MRI compatibility and MRA artifact testings. Furthermore, to verify maintenance of sterility for sterilization packages of i-ED COIL within the proposed shelf life, package integrity tests were carried out on the samples in reference to ASTM standards including F88/F88M and F2096.	All results of the aging tests met the acceptance criteria were the same as those of the performance testing. Therefore, three-years shelf-life of i-ED COIL was established.

The results from these tests demonstrate that the technological characteristics and performance criteria of the i-ED COIL System are adequate for the intended use of the device, and that the device can perform in a manner equivalent to devices currently distributed on the market with the same intended use.

Biocompatibility:

To demonstrate the biological safety of the body-contacting materials and substantial equivalence of the i-ED COIL to the predicate devices, the biocompatibility testing listed in Table 3 below was performed in accordance with "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"; Guidance for Industry and Food and Drug Administration Staff" (dated June 16, 2016):

Table 3 Summary of biocompatibility testing

Test item / Tested component	Test Method Summary	Results
Chemical Characterization by analysis of extracted substances / Platinum coil	In reference to USP<661> and ISO 10993-18, the test articles were extracted by one or more than one vehicle(s). The extracted substances were analyzed by multiple analysis including GC-MS, LC-MS and IC.	Analysis results showed that the platinum coil did not leach definite toxic substances.

Test item / Tested component	Test Method Summary	Results
Cytotoxicity / Platinum coil, Pusher and Sheath adapter	In reference to ISO 10993-5, cytotoxicity on V79 cells was examined by a colony formation assay using medium extract.	Not cytotoxic (the medium extract from test article did not inhibit colony formation of V79 cells)
Sensitization / Platinum coil, Pusher and Sheath adapter	In reference to ISO 10993-10, a skin sensitization test in guinea pigs was conducted using extracts of the platinum coil, Pusher or Sheath Adapter by physiological saline and olive oil.	No-skin sensitizing potency
	In reference to ISO 10993-10, a skin sensitization test in guinea pigs was conducted using extracts of the platinum coil by methanol.	No-skin sensitizing potency
Intracutaneous Reactivity / Platinum coil, Pusher and Sheath adapter	In reference to ISO 10993-10, the test and control solutions were intracutaneously injected into rabbits. The injection sites were macroscopically observed immediately after injection, and at 24, 48 and 72 hours after injection.	Acceptable intracutaneous reactivity
Acute Systemic Toxicity / Platinum coil, Pusher and Sheath adapter	In reference to ISO 10993-11, the test and control solutions prepared by extractions with vehicles were injected into mice. Observation of general conditions, measurement of body weight and necropsy were performed on the mice.	No acute systemic toxicity (test solution did not contain any substance having acute systemic toxicity)
Pyrogenicity (material mediated) / Platinum coil, Pusher and Sheath adapter	Material mediated rabbit pyrogen test was conducted according to ISO 10993-11 and USP <151>. The body temperature of the animals were measured before and after injection (multiple timepoints) of extract.	Non-pyrogenicity (none of the animals showed a body temperature rise of 0.5°C or more)
Genotoxicity / Platinum coil	In reference to ISO 10993-3 and OECD Guideline No. 471, bacterial reverse mutation test was conducted by the preincubation method with and without metabolic activation system (S9 mix) using tester strains.	Non-mutagenic (no mutagenic activity (negative))
	In reference to ISO 10993-3 and OECD Guideline No. 473, an *in vitro* chromosomal aberration test in CHL/IU cells.	Non-mutagenic (no induction of chromosomal aberrations)
Intramuscular Implantation / Platinum coil	In reference to ISO ISO 10993-6, platinum coils were implanted into paravertebral muscles of rabitts for 4 weeks and 13 weeks. The implantation sites were examined macroscopically and histologically.	No properties injurious to the paravertebral muscle of rabbits
Heamocompatibility / Platinum coil, Pusher and Sheath adapter	In reference to ASTM F756 and ISO 10993-4, a hemolysis test using human blood was conducted on both, the extract of the component obtained with PBS (-) (indirect contact condition; for Platinum coil, Pusher and Sheath adapter) and the component itself (direct contact condition; for Platinum coil and Pusher).	Non-hemolytic property
	In reference to ISO 10993-4, thrombogenicity (coagulation system: TAT and platete: β-TG) of the Pusher was evaluated.	It was judged the thrombogenesis risk was equivalent or lower to that of legally-marketed devices.
	Changes in complement factors (SC5b-9) after exposure of human serum or plasma to the	The complement activation by the platinum coil and the pusher was within the

Test item / Tested component	Test Method Summary	Results
	platinum coil or the pusher, *in vitro*, were examined.	acceptable range as a medical device.
Chronic Systemic Toxicity / Platinum coil	In reference to ISO 10993-11, the platinum coils were implanted subcutaneously in the back of rats for 26 weeks, and chronic systemic toxicity was evaluated.	The platinum coil did not cause any chronic systemic toxicities.
Carcinogenicity / Platinum coil	In reference to ISO 10993-17, toxicological Risk Assessment on extracted substances was conducted.	Non-carcinogenic

The results from these tests demonstrate that the i-ED COIL System is biocompatible for its intended use similar to the predicate devices.

Electrical safety and electromagnetic compatibility (EMC):

Electrical safety and EMC testing were conducted on the EDG v4, consisting of the power source and connection cables attached clips. The detachment system device complies with the IEC 60601-1 standard for the electrical safety and the IEC 60601-1-2 standard for the EMC.

Software Verification and Validation Testing:

Software verification and validation testing were conducted, and documentation was provided in this 510(k) submission as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (dated May 11, 2005).

Conclusions:

The i-ED COIL System met all of the predetermined acceptance criteria for the design verification and validation as specified by applicable standards, guidances, test protocols and/or customer inputs. The i-ED COIL System is substantially equivalent to legally marketed predicate devices.