March 26, 2021

Kaneka Medical America LLC
% Takeaki Miyata
Manager, Regulatory Affairs & Quality Assurance Team
Kaneka Corporation
1-12-32, Akasaka
Minato-ku, Tokyo 107-6028
Japan

Re: K210638
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: February 26, 2021
Received: March 3, 2021

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,

Naira Muradyan, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210638

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, K210638

i-ED COIL System

510(k) Submitter

Kaneka Medical America LLC
623 Fifth Avenue, New York
NY, 10022, The United States
Contact Person: Audra Bogucki
Telephone: 917-628-9870
Email: Audra.boguchi@kaneka.com

Official Correspondent

Takeaki Miyata
Manager, Regulatory Affairs & Quality Assurance Team
KANEKA CORPORATION
1-12-32 , Akasaka, Minato-ku,
Tokyo 107-6028, Japan
Phone: +81-3-5574-8023
Email: Takeaki.Miyata@kaneka.co.jp

Date Prepared: March 25, 2021

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:

- Predicate (original) device: i-ED COIL System [K192068 (Kaneka Corporation)]
- Reference device: InZone Detachment System [K160096 (Stryker Neurovascular)]

The predicate device and reference device 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 of vascular diseases 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.

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 Device

The i-ED COIL System has the same intended use (vascular and neurovascular embolization and permanent occlusion of blood flow) as the predicate device and InZone Detachment System. The indications for use of the i-ED COIL System is identical to that of the predicate device, and similar to that of the InZone Detachment System.

Comparison of Technological Characteristics to Predicate Device and Reference Device

Comparison table of the technological characteristics to the predicate, original i-ED COIL System, and reference device is provided in Table 1 below:

Table 1 Comparison table of technological characteristics

Characteristics	Predicate Device	Reference Device	Subject Device	Identicalness / similarity, or difference
	i-ED COIL System [K192068] (Kaneka Corporation)	InZone Detachment System [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	Vascular and neurovascular embolization and permanent occlusion of blood flow	Identical
Configuration of an embolization coil device	The i-ED COIL consists of an embolization coil implant comprised of platinum-tungsten alloy, affixed to a pusher (delivery wire) with a sheath adapter to facilitate insertion into the hub of a microcatheter.	Not applicable	The i-ED COIL consists of an embolization coil implant comprised of platinum-tungsten alloy, affixed to a pusher (delivery wire) with a sheath adapter to facilitate insertion into the hub of a microcatheter.	Identical to the predicate device

Table 1 Comparison table of technological characteristics

Characteristics	Predicate Device i-ED COIL System [K192068] (Kaneka Corporation)	Reference Device InZone Detachment System [K160096] (Stryker Neurovascular)	Subject Device i-ED COIL System (Kaneka Corporation)	Identicalness / similarity, or difference
Use environments	Hospital, interventional neuroradiology sites	Hospital, interventional neuroradiology sites	Hospital, interventional neuroradiology sites	Identical
Dimension/Shape of Coil				
Primary coil outer diameter (mm)	• Helical: 0.25 to 0.43 • Complex: 0.25 to 0.35	Not applicable	• Helical: 0.25 to 0.43 • Complex: 0.25 to 0.35	Identical to the predicate device
Secondary coil outer diameter (mm)	• Helical: 1.5 to 24.0 • Complex: 1.0 to 16.0	Not applicable	• Helical: 1.5 to 24.0 • Complex: 1.0 to 16.0	Identical to the predicate device
Primary coil length (mm)	10 to 500	Not applicable	10 to 500	Identical to the predicate device
Deployed coil shape	Helical, Complex	Not applicable	Helical, Complex	Identical to the predicate device
Pusher length (mm)	1870	Not applicable	1870	Identical to the predicate device
Pusher outer diameter (grip part; mm)	0.335	Not applicable	0.335	Identical to the predicate device
Dimension of Detachment device				
Dimension (mm)	125 × 55 × 25	140 × 58 × 28	125 × 55 × 25	Identical to the predicate device
Material of Detachable Coil				
Coil	Platinum-tungsten alloy	Not applicable	Platinum-tungsten alloy	Identical to the predicate device
Inner line (stretch resistance)	Polypropylene internal line (two lines)	Not applicable	Polypropylene internal line (two lines)	Identical to the predicate device
Pusher (main or core wire component)	Stainless steel	Not applicable	Stainless steel	Identical to the predicate device
Sheath	Polypropylene	Not applicable	Polypropylene	Identical to the predicate device
Specification of Detachment Device				
Coil detachment principle	Thermal fusing of PVA rod	Electrolytic dissolution of stainless steel	Thermal fusing of PVA rod	Identical to the predicate device
Circuit system	Mono-polar type	Bi-polar type or Mono-polar-type	Mono-polar type	Identical to the predicate device
Power source	Three AA (1.5V) alkaline batteries	Two AAAA (1.5 V) batteries	Three AA (1.5V) alkaline batteries	Identical to the predicate device

Characteristics	Predicate Device	Reference Device	Subject Device	Identicalness / similarity, or difference
	i-ED COIL System [K192068] (Kaneka Corporation)	InZone Detachment System [K160096] (Stryker Neurovascular)	i-ED COIL System (Kaneka Corporation)	
Output current/voltage	Alternate current (AC) up to 61.0 mA/ Voltage up to 22.5 V	2.4 mA maximum direct (DC)/ 28 VDC maximum output	Alternate current (AC) up to 61.0 mA/ Voltage up to 22.5 V	Identical to the predicate device
Detachments per unit	30 (based on the verification test result)	20	30 (based on the verification test result)	Identical to the predicate device
Sterilization Packaging Materials				
Detachable coil	Sterilization bag (film and Tyvek)	Not applicable	Sterilization bag (film and Tyvek)	Identical to the predicate device
Detachment device	Sterilization bag (film and Tyvek)	Blister packaging (PETG tray and Tyvek lid)	Blister packaging (PETG and Tyvek)	Similar to the reference device
Other Characteristics				
Radiopaque marker of pusher	Yes (Platinum coil part of pusher)	Not applicable	Yes (Platinum coil part of pusher)	Identical to the predicate device
Concomitantly used devices	Microcatheter, guiding catheter, rotating hemostatic valve (RHV)	Stryker Neurovascular detachable coils (Target, GDC, and Matrix)	Microcatheter, guiding catheter, rotating hemostatic valve (RHV)	Identical to the predicate device
Compatible microcatheter of coil (inner diameter: mm)	0.33 to 0.53 (depending on dimensional specification of a platinum coil)	Not applicable	0.33 to 0.53 (depending on dimensional specification of a platinum coil)	Identical to the predicate device
MRI compatibility of coil (stated in the IFU/DFU)	MR conditional	Not applicable	MR conditional	Identical to the predicate device
Sterilization method	EtO	EtO	EtO	Identical
Shelf-Life	Detachable coil (i-ED COIL) : Three years	Not applicable	Detachable coil (i-ED COIL): Three years	Identical to the predicate device
	Detachment device (EDG v4): Six months	Two years	Detachment device (EDG v4): Two years	The shelf-life of the EDG v4 is extended from six months to two years.

The subject device includes design changes to the sterilization packaging materials (change from a sterilization bag to a blister pack) and the shelf-life extension (from 6 months to 2 years) for the EDG v4. The change in the sterilization packaging materials is intended to improve the protection performance during the transportation, SAL (10^{-6}) and the sterilization method are not changed.

These modifications do not alter the intended use, indications for use, the fundamental scientific technology, or the performance specifications of the i-ED COIL System.

Performance Testing

To mitigate risks identified in our risk analysis of the modifications subject to this submission and to demonstrate substantial equivalence of modified i-ED COIL System to the predicate device, following tests were conducted using well-established methods:

Table 2 Summary of performance testing

Test	Test Method Summary	Results
Package integrity test on EDG v4	In order to verify integrity of the new sterilization packages of EDG v4, including maintenance of sterility, a package integrity test was carried out on samples that underwent simulated transportation in accordance with ASTM D4169-16. The used standards for the test included ASTM F1886/F1886M-16, F88/F88M-09, F1929-15 and F2096-11.	All samples passed the acceptance criteria.
Shipping and detachment test on EDG v4	In order to verify that the new package could protect the EDG v4 during transportation and the functionality was not impaired, testing including output measurements and operation check, and a detachment test using i-ED COILs were carried out on EDG v4 samples that had undergone simulated transportation challenge in accordance with ASTM D4169-16.	All samples passed the acceptance criteria.
Shelf-life testing on EDG v4	In order to expand the shelf-life of EDG v4, aging test was conducted on the samples that underwent simulated transportation (ASTM D4169-16) and accelerated-aging storage equivalent to two-years real-time aging (ASTM F1980-16). The test items were same as above-mentioned package integrity test and shipping and detachment test.	All samples passed the acceptance criteria.

The results from these tests demonstrate that the technological characteristics and performance of the modified i-ED COIL System are substantially equivalent to the predicate device.

Biocompatibility:

The modifications do not affect the nature of body contact for the EDG v4 (non-contact). Therefore, in the design control activities for the modifications, the original testing on the predicate device applies to the modified i-ED COIL System.

Conclusions:

The modified i-ED COIL System met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and customer inputs. The i-ED COIL System is substantially equivalent to the predicate device.