January 8, 2025

Ace Medical Industry Co., Ltd.
c/o Peter Chung
CEO
Plus Global
300, Atwood Street
Pittsburgh, PA 15213

Re: K242741
Trade/Device Name: ACE Cannula
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 8, 2024
Received: November 12, 2024

Dear Peter Chung:

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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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)*
K242741

Device Name
ACE Cannula

Indications for Use *(Describe)*
The ACE Cannula is intended to inject fluids intradermally.

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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K242741 510(k) Summary

1. Applicant information

1) Company: Ace Medical Industry Co., Ltd.
2) Address: 57-14, Gwangjeok-ro 228beon-gil, Yangju-si, Gyeonggi-do, Korea
3) Tel: 82-31-944-1182
4) Prepared date: January 8, 2025
5) Contact person: Peter Chung
6) Contact person address: 300, Atwood Street, Pittsburgh, PA, 15213, USA
7) Contact person Tel: 412-512-8802
8) Submission date: November 8, 2024

2. Device Information

1) Trade name: ACE Cannula
2) Common name: Hypodermic single lumen needle
3) Regulation name: Needle, Hypodermic, Single Lumen
4) Product code: FMI
5) Regulation number: 880.5570
6) Class of device: Class II
7) Panel: General Hospital

3. The legally marketed device to which we are claiming equivalence

K200017, Eclipse Medcorp LLC. / Eclipse DermaFlex Cannula

4. Device description

The ACE Cannula is provided as a single-use, sterile device. It is comprised of needles, hub and cap. This device comes in a variety of needle gauges and lengths. This device offers AN type and B type within the package. The AN type is a hypodermic single lumen needle intended to prepare the site for injection. The tip of this pilot needle is sharpened at one end, while the other end is joined to a hub.

The B type has a metal tube with the tip, which is closed and blunt, while the cannula has an opening laterally at a lower point under the tip. On the other end, the device is joined to a female connector(hub) designed to mate with a male connector(nozzle) of a piston syringe or secondary medication sets to prepare and administer fluids/medications/drugs to a patient. The thirteen models are as follows: AN-2125, AN-2325, AN-2613, AN-2625, AN-2725, B-2260, B-2270, B-2540, B-2550, B-2725, B-2738, B-2750, and B-3025.

Model	Gauge	Length of needle (㎜)	Out diameter of needle (㎜)
AN-2125	21	25	0.800~0.830
AN-2325	23	25	0.600~0.673
AN-2613	26	13	0.440~0.470
AN-2625	26	25	0.440~0.470
AN-2725	27	25	0.400~0.420
B-2260	22	60	0.698~0.730
B-2270	22	70	0.698~0.730
B-2540	25	40	0.500~0.530
B-2550	25	50	0.500~0.530
B-2725	27	25	0.400~0.420
B-2738	27	38	0.400~0.420
B-2750	27	50	0.400~0.420
B-3025	30	25	0.298~0.320

5. Indications For Use

The ACE Cannula is intended to inject fluids intradermally.

6. Performance data:

1) Bench tests for the device's performance were conducted. Bench testing includes mechanical testing, sterility testing including EO residues. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

Requirements – Test (ISO 7864)	Result
Appearance	Pass
Color coding (Section 4.7)	Pass
Color of hub (Section 4.8.2)	Pass
Needle tube Tolerance on length (Section 4.10.2)	Pass
Needle tube Freedom from defects (Section 4.10.3)	Pass
Needle point (Section 4.11)	Pass
Bond between hub and needle tube (Section 4.12)	Pass
Patency of lumen (Section 4.13)	Pass

Requirements – Test (ISO 9626)	Result
Dimension (Section 5.6.)	Pass
Stiffness (Section 5.8.)	Pass
Resistance to breakage (Section 5.9.)	Pass
Resistance to corrosion (Section 5.10)	Pass

Requirements – Test (ISO 80369-7, ISO 80369-20)	Result
Leakage by pressure decay (ISO 80369-7: 6.1.2, ISO 80369-20: Annex B)	Pass
Positive Pressure Liquid Leakage (ISO 80369-7: 6.1.3, ISO 80369-20: Annex C)	Pass
Sub-atmospheric Pressure Air Leakage (ISO 80369-7: 6.2, ISO 80369-20: Annex D)	Pass
Stress Cracking (ISO 80369-7: 6.3, ISO 80369-20: Annex E)	Pass
Resistance to separation from axial load (ISO 80369-7: 6.4, ISO 80369-20: Annex F)	Pass
Resistance to separation from unscrewing (ISO 80369-7: 6.5, ISO 80369-20: Annex G)	Pass
Resistance to overriding (ISO 80369-7: 6.6, ISO 80369-20: Annex H)	Pass
Disconnection by unscrewing (ISO 80369-20, Annex I)	Pass

Test item	Requirements	Result
Extraction: pH	Difference of pH shall be ≤ 1.0	Pass
Extraction: Potassium permanganate reducing substances	Difference of the consumption shall be ≤ 2.0 mL	Pass
Extraction: Residue on evaporation	Amount of residue shall be ≤ 1.0 mg	Pass
Extraction: Pb, Fe, Sn, Zn	Total content of heavy metals shall be ≤ 5.0 mg/L	Pass
Extraction: Cd	Content of Cd shall be ≤ 0.1 mg/L	Pass

2) Biocompatibility

Biocompatibility of the ACE Cannula / Duo Cannula / Q Micro Cannula was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "External communication device – Blood path indirect" with a contact duration of "Limited (< 24 hours)". The following tests were

performed, as recommended: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. All evaluation acceptance criteria were met.

Test item	Test method / Test criteria	Test result
Cytotoxicity test	When it was tested accordingly to ISO 10993-5, tests for in vitro cytotoxicity-Test on extracts method, it should satisfy the requirements.	Pass
Hemolysis test	When it was tested accordingly to ISO 10993-4, Selection off tests for interactions with blood-evaluation of hemolytic properties of medical devices and medical device materials, it should satisfy the requirements.	Pass
Intracutaneous reactivity test	When it was tested accordingly to ISO 10993-10, Tests for irritation and skin sensitization-Animal intracutaneous (Intradermal) reactivity test, it should satisfy the requirements.	Pass
Skin sensitization test	when it was tested accordingly to ISO 10993-10, Tests for irritation and skin sensitization-Guinea pig maximization test (GPMT), it should satisfy the requirements.	Pass
Acute systemic toxicity test	When it was tested accordingly to ISO 10993-11, Tests for systemic toxicity-Acute systemic toxicity, it should satisfy the requirements.	Pass
Pyrogen Test	When it was tested accordingly to ISO 10993-11, Tests for systemic toxicity-Information on material-mediated pyrogens, it should satisfy the requirements.	Pass
Particulate Matter Injection	USP <788>, Particulate Matter for Injections (Method 1 Light Obscuration Particle Count Test). Test result should satisfy the requirements described in the USP <788>.	Pass

3) Sterility and LAL test

The sterilization method has been validated to ISO 11135, which has thereby determined the routine control and monitoring parameters. The testing is performed according to the following standards:

Test item	Test standard	Test result
LAL test	USP39 <85>, Bacterial Endotoxins Test (Unit : EU/Device)	Pass
E.O sterilization validation	According to ISO 11135:2014 E.O 30%, CO_2 70% Temperature: 50 ±7℃ Exposure time: 5 hours	Pass
Sterility test	According to ISO 11737-2	Pass
E.O Residual test	Under the conditions of ISO 10993-7:2008, Ethylene oxide sterilization residuals, the test articles should meet the test requirements.	Pass

7. Predicate device comparison table

Manufacturer	ACE Medical Industry Co., Ltd.	Eclipse Medcorp. LLC.	Remark
510(K) No.	K242741	K200017	N/A
Device name	ACE Cannula (13 models including AN-2260)	Eclipse DermaFlex Cannula	N/A
Indications for use	The ACE Cannula, Duo Cannula, Q Micro Cannula is intended to inject fluids intradermally.	The Eclipse DermaFlex Cannula is intended to inject fluids intradermally.	Identical
Principle of Operation	This device is used in conjunction with a piston syringe to deliver fluids/medications/drugs into the body. The device consists of a metal tube(needle), joined to a female connector(hub). This device comes in a variety of needle gauges and lengths.	This device is used in conjunction with a piston syringe to deliver fluids/medications/drugs into the body. The device consists of a metal tube(needle), joined to a female connector(hub). This device comes in a variety of needle gauges and lengths.	Identical
Structure	Hub, Needle, Protective Cap	Hub, Needle, Protective Cap	Identical

Needle Length	13, 25, 38, 40, 50, 60, 70mm	25, 38, 40, 50, 60, 70mm	Different #1
Needle Gauge	21G, 22G, 23G, 25G, 26G, 27G, 30G	21G, 22G, 23G, 25G, 26G, 27G, 30G	Identical
Tip configuration	Sharpened tip (pilot needle) Closed blunt tip with lateral opening (intradermic needle)	Sharpened tip (pilot needle) Closed blunt tip with lateral opening (intradermic needle)	Identical
Hub structure	Luer Taper	Luer Taper	Identical
Material			Identical
Hub of needle	Polypropylene (PP)	Polypropylene (PP)	
Protective Cap	Polypropylene (PP)	Polypropylene (PP)	
Cannula	Stainless Steel 304	Stainless Steel 304	
Adhesive	Epoxy Resin	Epoxy Resin	
Lubricant	Silicone	Silicone	
Needle Performance Requirements	Comforms to the following standards: ISO 7864 : 2016 Sterile hypodermic needles for single use — Requirements and test methods ISO 9626 : 2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Complies to the following standards: ISO 7864 : 2016 Sterile hypodermic needles for single use — Requirements and test methods ISO 9626 : 2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Identical
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Identical
	Cytotoxicity Hemolysis test Pyrogen test Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	Cytotoxicity Hemolysis test Pyrogen test Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	
Sterilization	E.O sterilization	E.O sterilization	Identical
SAL	10^{-6}	10^{-6}	Identical
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Identical

Equivalence Discussion

Different #1: Length of needle

The subject device has a very similar range of needle length. However, it additionally has a 13 mm length configuration, and this needle length is not included in the configuration of the legally marketed device (K200017). However, this needle configuration is widely used in the clinical field. Also, the different needle configurations present do not affect the indications for the use of the equipment itself. To validate this claim, performance testing for the needle component was conducted. In accordance with internationally recognized standards (ISO 7864, ISO 9626), it has been proved that the needle configuration of the proposed device conforms with the relevant standard. Therefore, the differences in configuration do not raise any new questions about its safety and/or effectiveness.

8. Sterility, Shipping and Shelf-Life

Sterilization validation was performed in accordance with ISO 11135:2014 to prove that the E.O Gas sterilization process has been suitable for continuous production. Through validation, the sterilization process was deemed acceptable.

Also, the device's Shelf life of 3 years is validated in accordance with ISO 11607-1:2006 and ISO 11607-2:2006. Lastly, per ASTM D4169-22, it was confirmed that the product conforms with the requirements.

9. Conclusion

The device is investigated for function to compare the operation of function between ACE Cannula and predicate devices. Test results demonstrate that the specifications and performance of the device are substantially equivalent to the legally marketed predicate device.

Therefore, it is concluded that ACE Cannula is substantially equivalent to the legally marketed predicate device.