February 16, 2023

Shanghai Kindly Enterprise Development Group Co., Ltd
% Evan Hu
Marketing & Technical Manager
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, Shanghai 201114
China

Re: K223327
Trade/Device Name: Sterile Aesthetic Cannula and Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 10, 2023
Received: February 13, 2023

Dear Evan Hu:

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,

Alan M. Stevens -S3

CAPT Alan Stevens
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223327

Device Name
Sterile Aesthetic Cannula and Hypodermic Needle

Indications for Use *(Describe)*
The product is intended to use for injecting fluids intradermally. It is for adult only (greater than 21 years old).

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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1. **Preparation date: 02/13/2023**

2. **Submitter**

Manufacturer: Shanghai Kindly Enterprise Development Group Co., Ltd.
Address: No.658 Gaochao Road, 201803, Shanghai, China
Contact person: Liu Hualong, 86-02169118232, henry_liu@kdlchina.net
Submission correspondent: Evan Hu, 86-18616124827, Evan.hu@mind-link.net

3. **Device**

Trading name: Sterile Aesthetic Cannula and Hypodermic Needle
Common name: Aesthetic needle
Regulation No.: 21 CFR 880.5570
Classification name: Needle, Hypodermic, Single Lumen
Classification: Class II
Product code: FMI

4. **Predicate device**

Predicate device: K200017-Eclipse DermaFlex Cannula

5. **Device description**

The Sterile Aesthetic Cannula and Hypodermic Needle is a combined medical device, including a blunt needle-cannula and a hypodermic needle-sharp needle. The sharp needle consists of a needle hub, a needle, and a protective cap. The blunt needle-cannula consists of a needle hub, a blunt cannula, and a protective cap.
The device is provided for single-used, sterilized, and prescription use only. It offers various model configurations, including multiple needle gauge sizes, lengths, and tips, to fit most usage scenarios. Details of the specification refer to Table 1.

Table 1. Device specifications

Cannula (Blunt needle)			Sharp needle (Normal needle)		
Gauge(G)	Length(mm)	Wall type	Gauge(G)	Length(mm)	Wall type
Group A: Only cannula					
22	40, 50, 60, 70, 90	ETW	N/A		
23	30, 40, 50, 60	ETW			
25	30, 40, 50, 60	ETW			
26	13, 25, 30, 40	ETW			
27	13, 25, 30, 40	ETW			
30	13, 25, 30	ETW			
Group B: Cannula and sharp needle with the same gauge					

22	40	ETW	22	25	TW
22	50	ETW	22	25	TW
22	70	ETW	22	25	TW
23	30	ETW	23	25	TW
23	40	ETW	23	25	TW
23	50	ETW	23	25	TW
25	30	ETW	25	16	TW
25	40	ETW	25	16	TW
25	50	ETW	25	16	TW
26	13	ETW	26	16	RW
26	25	ETW	26	16	RW
27	13	ETW	27	13	RW
27	25	ETW	27	13	RW
27	40	ETW	27	13	RW
27	50	ETW	27	13	RW
30	13	ETW	30	13	RW
30	25	ETW	30	13	RW
Group C: Cannula and sharp needle with different gauges					
22	20	ETW	21	25	TW
22	25	ETW	21	25	TW
22	40	ETW	21	25	TW
22	50	ETW	21	25	TW
22	70	ETW	21	25	TW
23	40	ETW	22	25	TW
23	50	ETW	22	25	TW
23	70	ETW	22	25	TW
24	40	ETW	23	25	TW
24	50	ETW	23	25	TW
25	38	ETW	24	25	TW
25	50	ETW	24	25	TW
25	70	ETW	24	25	TW
26	13	ETW	25	25	TW
26	25	ETW	25	25	TW
26	35	ETW	25	25	TW
26	40	ETW	25	25	TW
26	50	ETW	25	25	TW
27	13	ETW	26	25	RW
27	25	ETW	26	25	RW
27	40	ETW	26	25	RW
27	50	ETW	26	25	RW
30	13	ETW	29	13	RW
30	25	ETW	29	13	RW
30	38	ETW	29	13	RW

6. Indications for use/Intended use

The product is intended to use for injecting fluids intradermally. It is for adult only (greater than 21 years old).

7. Comparison of technological characters between proposed and predicate devices

Table 2. Characters comparison

Characters	Proposed device (K223327- Sterile Aesthetic Cannula and Hypodermic Needle)	Predicate device (K200017-Eclipse DermaFlex Cannula)	Comments
Indications for use	The product is intended to use for injecting fluids intradermally. It is for adult only (greater than 21 years old).	The Eclipse DermaFlex Cannula is intended to inject fluids intradermally.	Same
Product code	FMI	FMI	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	Same
Structure and materials	Needle hub: PP Protective cap: PP (cannula and sharp needle), PE (cannula) Needle tube: SUS 304 Lubricant: Silicone oil Adhesive: Epoxy resin, UV resin	Needle hub: PP Protective cap: PP Needle tube: SUS 304 Lubricant: Silicone oil	#1
Color coding	Meet requirements of ISO 6009	Meet requirements of ISO 6009	Same
Needle gauge	Cannula: 22, 23, 24, 25, 26, 27, 30G Sharp needle: 21, 22, 23, 24, 25, 26, 27, 29, 30G	Cannula: 21, 22, 23, 25, 26, 27, 30G Sharp needle: 21, 22, 23, 25, 26, 27, 30G	#2
Needle length	Cannula: 13, 25, 35, 38, 40, 50, 70mm Sharp needle: 13, 16, 25mm	Cannula: 25, 38, 40, 50, 60, 70mm Sharp needle: 25, 38, 40, 50, 60, 70mm	#3
Tip configuration	Sharp needle: sharpened tip Cannula: closed blunt tip with lateral opening	Sharp needle: sharpened tip Cannula: closed blunt tip with lateral opening	Same
Connection to syringe	Luer taper	Luer taper	Same
Physical performance	Meet requirements of ISO 9626, ISO 7864 and ISO 80369-7	Meet requirements of ISO 9626, ISO 7864 and ISO 80369-7	Same
Biocompatibility performance	Meet requirements of ISO 10993-1, -4, -5, -10, -11	Meet requirements of ISO 10993-1, -4, -5, -10, -11	Same
Sterilization method	Sterilized by EO gas SAL 10^{-6}	Sterilized by EO gas SAL 10^{-6}	Same

#1: The materials used for manufacturing protective cap are different. The function of the protective cap is for needle protection before use. The different materials do not raise new questions of safety or effectiveness. Performance data results also showed all testing met the requirements of standards or guidance.

#2 and #3: The proposed device's needle gauge specification range is within the predicate device's range. However, the proposed device has shorter needle lengths (13mm and 16mm) than the predicate device. Shorter needle lengths offer options for end users' choice. The performance of needles with shorter lengths was tested in compliance with ISO 9626 and ISO 7864. Performance data results showed all testing met the requirements of standards or guidance. The different needle lengths do not raise new questions of safety and effectiveness.

8. Non-clinical testing

PERFORMANCE TESTING

The proposed device was tested in compliance with ISO 7864:2016 and ISO 9626:2016 for evaluating the overall non-clinical performance. Additionally, luer connector testing in compliance with ISO 80369-7:2016 and ISO 80360-20:2015 was completed. The performance and design testing results met the standards' requirements.

BIOCOMPATIBILITY TESTING:

The proposed device was tested in compliance with the 2020 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", as the Externally Communicating Device, Blood Path Indirect, Limited Contact (< 24hrs). Biocompatibility testing was conducted as following items.

- Acute systemic toxicity
- Pyrogenicity
- Skin sensitization
- Intracutaneous reactivity
- In-vitro hemolytic
- In-vitro cytotoxicity

Residual particles and Endotoxin were tested in compliance with USP <788> and USP <85>/USP <161>, respectively.

STERILE, PACKAGE, AND SHELF-LIFE VALIDATION:

The sterilization method by using Ethylene Oxide (EO) gas was validated in compliance with ISO 11135:2014 to achieve the sterility assurance level (SAL) of 10^{-6}.

EO and Epoxy Chlorohydrin (ECH) residuals met the limit requirements of ISO 10993-7:2008, and Pyrogen testing met the requirements of USP <151> 0.9% saline injection method.

The Shelf-Life validation study was conducted under accelerated aging condition in compliance with ASTM F1980-16 to verify the claimed shelf-life of 5 years.

Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging was deemed acceptable for protection of product and sterility maintenance.

Sterile barrier testing was conducted in compliance with the following FDA recognized consensus standards.

- Seal Strength ASTM F88/F88-15
- Dye penetration ASTM F1929-15
- Internal Pressurization ASTM F1140/F1140M:2013
- Sterility USP <71>

9. Clinical testing

Not applicable for this submission**.**

10. Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use, technological characteristics, and performance.