August 18, 2022

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: K212972
Trade/Device Name: KDL Safety Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 8, 2022
Received: July 18, 2022

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,

CAPT Alan M. 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)*
K212972

Device Name
KDL Safety Needles

Indications for Use *(Describe)*
The safety needles are intended to be used with a Luer slip or Luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K212972 510(k) SUMMARY

1. **Preparation date: 8/16/2022**

2. **Submitter**

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

3. **Device**

Trade name: KDL Safety Needles
Common name: Safety needle
Regulation Number: §21 CFR 880.5570
Classification name: Hypodermic Single Lumen Needle
Classification: Class II
Product code: FMI

4. **Predicate device**

TK Safety Needle (K191644), FMI, §21 CFR 880.5570

5. **Device description**

The KDL Safety Needle is a hypodermic needle with a hinged safety sheath attached to the needle hub. The safety sheath could be manually activated when the needle is withdrawn from the body before disposal, minimizing the risk of needle sharps injury during disposal. It is activated manually by hand or any solid surface.
The self-locking mechanism is positioned within the center and the proximal end of the sheath. The hinge structure could let clinical personnel flexibly adjust the sheath to the designed position for use.
The KDL Safety Needle has various colors, needle gauge sizes, and needle length sizes, which could be applied in different clinic-use scenarios. Meanwhile, the KDL Safety Needle is sterilized by ethylene oxide and without any pyrogen or latex.

Table 1. Device models

Birmingham gauge	Length (mm)	Needle cutting edge	Needle wall
18G	25, 32, 38, 50	SB, LB	RW, TW
19G	25, 32, 38, 50	SB, LB	RW, TW
20G	25, 32, 38, 50	LB	RW, TW
21G	25, 32, 38, 50	LB	RW, TW

22G	25, 32, 38, 50	LB	RW, TW
23G	25, 38	LB	RW, TW
24G	20, 25	LB	RW, TW
25G	16, 25, 38	LB	RW, TW
26G	9, 13	SB, LB	RW, TW
27G	6, 8, 9, 12, 13, 15	SB, LB	RW, TW
28G	6, 8, 12, 15	SB, LB	RW, TW
29G	6, 8, 12, 15	SB, LB	RW, TW
30G	6, 8, 9, 12, 13, 15	SB, LB	RW, TW

The KDL Safety Needles are available in various models, mainly 13 types with different needle lengths and configurations and a total of 120 sub-types, as shown in Table 1.

6. Indications for Use/Intended Use

The safety needles are intended to be used with a Luer slip or Luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.

7. Comparison of technological characters between proposed and predicate devices

Table 2. Characters comparison

Characters	Proposed device (K212972- KDL Safety Needles)	Predicate device (K191644- TK Safety Needle)	Remark
Product code	FMI	FMI	Same
Indications for Use	The safety needles are intended to be used with a Luer slip or Luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.	TK Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TK Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.	Similar 1
Prescription or over-the-counter use	Prescription	Prescription	Same
Material: Needle hub Needle	 Polypropylene Stainless steel	 Polypropylene Stainless steel	Same

Needle sheath Adhesive Lubricant	Polypropylene Epoxy sizes Silicone oil	Polypropylene Epoxy sizes Silicone oil	
Needle Gauge and length	18G: 25, 32, 38, 50mm 19G: 25, 32, 38, 50mm 20G: 25, 32, 38, 50mm 21G: 25, 32, 38, 50mm 22G: 25, 32, 38, 50mm 23G: 25, 38mm 24G: 20, 25mm 25G: 9, 13, 16, 25, 38mm 26G: 9, 13mm 27G: 6, 8, 9, 12, 13, 15mm 28G: 6, 8, 12, 15mm 29G: 6, 8, 12, 15mm 30G: 6, 8, 9, 12, 13, 15mm	16G: 1 to 1 1/2" 17G: 1 to 1 1/2" 18G: 1 to 1 1/2" 19G: 1 to 1 1/2" 20G: 1 to 1 1/2" 21G: 1 to 1 1/2" 22G: 1 to 1 1/2" 23G: 1 to 1 1/2" 24G: 1 to 1 1/2" 25G: 1 to 1 1/2" 26G: 1 to 1 1/2" 27G: 1 to 1 1/2" 28G: 1/2 to 1" 29G: 1/2 to 1" 30G: 1/2 to 1"	Different 1
Tip configuration	Bevel	Bevel	Same
Protective feature	Extra safety sheath Meet ISO 23908	Extra safety sheath Meet ISO 23908	Same
Color	Per ISO 6009	Per ISO 6009	Same
Sterility	Sterilized by EO	Sterilized by EO	Same
Single-use	Single-use	Single-use	Same
Physical performance	Meet ISO 7864 and ISO 9626	Meet ISO 7864 and ISO 9626	Same
Biocompatibility	Meet ISO 10993	Meet ISO 10993	Same

Similar 1: The intended use of the proposed and predicate device is the same that is intended for fluid aspiration and injection. Meanwhile, they both have the same safety protection features. The only difference is that the indications for use of the predicate device includes its trade name. It does not impact the device's safety and effectiveness.

Different 1: 1" is equal to 25.4mm. The needle length range of the predicate device is 13 to 38mm for various gauges. However, the proposed device has models that are longer length (50mm) and shorter length (6~12mm). The difference in needle length could impact the device's performance, so performance testing were conducted to cover the difference. The results demonstrate that device performances of selected models (including 6, 8, 9, 12 and 50mm) meet the requirements of ISO 7864 and ISO 9626. Therefore, the difference in needle length does not impact the device's safety and effectiveness.

8. Non-clinical testing results

The non-clinical tests of this proposed device are tested in conformance with the following standards.

(1) Physical performance testing:

(a) ISO 7864:2016, Sterile hypodermic needles for single use.
(b) ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications - part 7: Connectors for intravascular or hypodermic applications.
(c) ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Device.
(d) ISO 6009:2016 Hypodermic needles for single use - Colour coding for identification
(e) ISO 23908:2011, Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

(2) Sterility:

(a) ISO 11135:2014 Sterilization of healthcare products - Ethylene oxide -Requirements for the development, validation and routine control of a sterilization process for medical devices.
(b) ISO 11138-2:2017 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes.
(c) ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
(d) ISO 11737-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
(e) ISO 10993-7:2008/AMD 1:2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants.
(f) EN 868-7:2017, Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods
(g) EN 868-1:1997, Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods
(h) ASTM F1140: 2020, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
(i) ASTM F88: 2015, Standard Test Method for Seal Strength of Flexible Barrier Materials
(j) ASTM F1929: 2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

(3) Biocompatibility testing:

(a) ISO10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
(b) ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood.
(c) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

(d) ISO 10993-10:2010, Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization.
(e) ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity and Pyrogenicity
(f) USP <161> Medical Devices—Bacterial Endotoxin test
(g) USP <788> Particulate Matter for Injections

9. Clinical testing

No clinical testing is available for this device.

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 and technological characteristics.