August 23, 2022

Hantech Medical Device Co., Ltd.
Arnold YANG
Mr.
No 288, Sanheng Road Changhe Industridal Park, Cixi
Ningbo, Zhejiang 315326
China

Re: K220603
Trade/Device Name: Disposable Medical Safety Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 15, 2022
Received: July 19, 2022

Dear Arnold YANG:

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 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)*
K220603

Device Name
Disposable Medical Safety Hypodermic Needle

Indications for Use *(Describe)*
The Disposable Medical Safety Hypodermic Needle is intended for use in the aspiration and injection of fluids for medical purposes. The Disposable Medical Safety Hypodermic 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.

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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K220603 510(k) summary

I Submitter

Device submitter: Hantech Medical Device Co., Ltd.
No 288, Sanheng Road Changhe Industridal Park, Cixi 315326, Ningbo
PEOPLE'S REPUBLIC OF CHINA

Contact person:
Name: Arnold YANG
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Date: 07/15/2022

II Device

Trade Name of Device: Disposable Medical Safety Hypodermic Needle
Common Name: Hypodermic Single Lumen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product code: FMI
Review Panel: General Hospital

III Predicate Devices

Trade name:	TK Safety Needle
Common name:	Hypodermic Single Lumen Needle
Classification:	Class II, 21 CFR 880.5570
Product Code:	FMI
Premarket Notification:	K191644
Manufacturer:	Anhui Tiankang Medical Technology Co., Ltd

IV Device description

The Disposable Medical Safety Hypodermic Needle is composed of a needle hub, a needle tube, a needle cap and a sharp injury protection feature. The sharp injury protection feature is simultaneously activated when manually pressed over the needle after use and prior to disposal to minimize the possibility of sharps injury. The sharp injury protection feature is activated with one-hand operation by pressing the

sharp injury protection feature either with the finger or thumb, or by surface activation. The locking mechanism is positioned within the center and proximal end of the sharp injury protection feature. The hinge feature(sharp injury protection feature) allows the medical practitioner the flexibility to adjust the sharp injury protection feature to its desired position for use.

Device	Needle length	Needle gauge	Type of wall	Blade angle
Disposable Medical Safety Hypodermic Needle	1/2", 5/8", 1", 1 1/4", 1 1/2"	30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G	TW RW ETW	SB LB
Note1: Where “RW” represents regular wall, “TW” represents thin wall, “ETW” represents extra thin wall, “LB” stands for long bevel angle, “SB” stands for short bevel angle. Note 2: G in the specification is the gauge specification				

V Indications for use

The Disposable Medical Safety Hypodermic Needle is intended for use in the aspiration and injection of fluids for medical purposes. The Disposable Medical Safety Hypodermic 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.

VI Comparison of technological characteristics with the predicate devices

The Disposable Medical Safety Hypodermic Needle have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate device. The differences between the Disposable Medical Safety Hypodermic Needle and predicate device do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K191644	Comments
Indications for use	The Disposable Medical Safety Hypodermic Needle is intended for use in the aspiration and injection of fluids for medical purposes. The Disposable Medical Safety Hypodermic Needle is compatible for use with standard luer slip and luer	The 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.	Similar

Device feature	Subject Device	Predicate Device K191644	Comments
	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.	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.	
Product code	FMI	FMI	Similar
Regulation number	21 CFR 880.5570	21 CFR 880.5570	Similar
Class	CLASS II	CLASS II	Similar
Principle of operation	Normal	Normal	Similar
Needle gauge	30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G	16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Substantially equivalent Comment 1
Length	1/2", 5/8", 1", 1 1/4", 1 1/2"	1/2 to 1" , 1 to 1 1/2"	
Type of wall	Thin Wall, Regular Wall or Extra Thin Wall	From 16G to 23G: Thin Wall From 24G to 30G: Regular Wall	
Blade angle	Short bevel or long bevel	Bevel	
Materials	Needle Hub: Polypropylene Needle Tube: Stainless Steel Needle Sheath: Polypropylene	Needle Hub: Polypropylene Needle: Stainless Steel Needle Sheath: Polypropylene	Similar
Sharps injury Prevention Features	Needle safety shield	Needle safety shield	Similar
Lubricant for Needle	Silicone Oil	Silicone Oil	Similar
Adhesive	Epoxy Sizes	Epoxy Sizes	Similar
Performance specifications	Conforms to ISO 7864	Conforms to ISO 7864	Similar
Sterilization	EO sterilization	EO sterilization	Similar
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993	Similar
Labeling	Meet the requirements of	Meet the requirements	Similar

Device feature	Subject Device	Predicate Device K191644	Comments
	21 CFR Part 801	of 21 CFR Part 801	

Discussion:

The subject device's needle gauge, needle length, type of wall and needle bevel are different from the predicate device. However, this difference is just in dimension. Different needle specification will be selected by physician per patient's condition. This difference does not affect intended use. In addition, differences were addressed through ISO 7864, ISO 9626 and ISO 80369-7. Therefore, the differences on needle length, gauge, wall type and bevel does not affect substantially equivalence on safety and effectiveness.

VII Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Disposable Medical Safety Hypodermic Needle 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	ISO 10993-5: 2009
Skin sensitization	ISO 10993-10: 2010
Hemolysis	ISO 10993-4: 2017
Intradermal reactivity	ISO 10993-10: 2010
Acute systemic toxicity	ISO 10993-11: 2017
Pyrogenicity	ISO 10993-11: 2017

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Disposable Medical Safety Hypodermic Needle is determined based on stability study which includes ageing test.

The testing is performed according to the following standards:

- ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

- ISO 11607-1: 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Performance testing

Performance testing is performed according to the following standards:

- ISO 7864: 2016

Cleanliness	Clause 4.3 of ISO 7864: 2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864: 2016
Limits for extractable metals	Clause 4.5 of ISO 7864: 2016
Tubular needle designation	Clause 4.6 of ISO 7864: 2016
Colour coding	Clause 4.7 of ISO 7864: 2016
Needle hub	Clause 4.8 of ISO 7864: 2016, ISO 80369-7 and ISO 6009
Needle cap	Clause 4.9 of ISO 7864: 2016
Needle tube (Tolerance on length, Freedom from defects, Lubricant)	Clause 4.10 of ISO 7864: 2016
Needle Point	Clause 4.11 of ISO 7864: 2016
Bond between Tube and Hub	Clause 4.12 of ISO 7864: 2016
Patency of Lumen	Clause 4.13 of ISO 7864: 2016

- ISO 9626:2016

Surface finish and visual appearance	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

- ISO 80369-7:2016

Dimensional requirements for luer connectors.	Clause 5 of ISO 80369-7: 2021
Fluid leakage (Positive pressure liquid leakage)	Clause 6.1.3 of ISO 80369-7: 2021
Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-7: 2021
Stress cracking	Clause 6.3 of ISO 80369-7: 2021
Resistance to separation from axial load	Clause 6.4 of ISO 80369-7: 2021
Resistance to separation from unscrewing	Clause 6.5 of ISO 80369-7: 2021
Resistance to overriding	Clause 6.6 of ISO 80369-7: 2021

- ISO 23908 and Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff

Activation torque
Protection features separating force
Resistance to breakage
Simulated Clinical Use Testing Report

VIII Conclusion

The Disposable Medical Safety Hypodermic Needle is substantially equivalent to its predicate device (TK Safety Needle). The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.