December 6, 2022

Anhui Tiankang Medical Technology Co., Ltd.
Zhang Yong
Management
No.228,Weiyi Road, Economic Development Zone
Tianchang, Anhui 239300
China

Re: K222385
Trade/Device Name: Bifurcated Needle
Regulatory Class: Unclassified
Product Code: LDH
Dated: November 10, 2022
Received: November 10, 2022

Dear Zhang Yong:

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 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)*

K222385

Device Name
Bifurcated Needle

Indications for Use *(Describe)*

The Bifurcated Needle is intended for use in administering vaccines by the scarification method or administering epidermal allergens.

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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K222385 510(k) Summary

I Submitter

Device submitter: Anhui Tiankang Medical Technology Co., Ltd.
No.228, Weiyi Road, Economic Development Zone, Tianchang City, Anhui, China.

Contact person:
Name: Zhang yong
Title: Management representative
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Fax: +86-550-7309158
E-mail: zy@tkmedical.com

Preparation Date**:** December 6, 2022

II Device

Trade Name of Device: Bifurcated Needle
Common Name: System, Delivery, Allergen And Vaccine
Regulation Name: None
Regulatory Class: Unclassified
Product code: LDH
Review Panel: General Hospital

III Predicate Devices

Trade name:	BD Bifurcated Needle
Common name:	Bifurcated Needle
Classification:	Unclassified
Product Code:	LDH
Premarket Notification:	K020523
Manufacturer:	BECTON, DICKINSON & CO.

IV Device description

The proposed Bifurcated Needle have two prongs. A small drop of smallpox vaccine was placed between the prongs and approximately fifteen punctures would be made into the skin. The needles were sterilized by EO to achieve a SAL of 10^{-6} and supplied sterile in packaging with a shelf life of five years.

V Indications for use

The Bifurcated Needle is intended for use in administering vaccines by the scarification method or administering epidermal allergens.

VI Comparison of technological characteristics with the predicate devices

The Bifurcated Needle has the same intended use, technology, design and biocompatibility is either identical or substantially equivalent to existing legally marketed predicate devices. The comparison between the subject device and the predicate devices are listed in below tables:

Table 6-1 Substantial equivalence discussion for Bifurcated Needle

Device feature	Subject Device K222385	Predicate Device K020523	Comment
Product	Bifurcated Needle	BD Bifurcated Needle	/
Indications for use	The Bifurcated Needle is intended for use in administering vaccines by the scarification method or administering epidermal allergens.	The BD Bifurcated Needle is intended for use in administering vaccines by the scarification method or administering epidermal allergens.	Same
Product code	LDH	LDH	Same
Principle of operation	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	Same
Models	BFN001	301754; 301755; 301756; 301757	Difference comment 1
Needle Length	64mm±0.3mm Needle	60.325mm	
Needle dimension	2mm±0.05mm	1.905mm	
Materials	Bifurcated needle-(SUS 304) Needle tip protector-(PVC MT)	Stainless steel	Difference comment 2
Sterilization	EO Sterilization	Sterilization	Difference comment 3

Device feature	Subject Device K222385	Predicate Device K020523	Comment
Biocompatibility	Contact level: blood path, indirect, limited contact (<24 hours). Conforms to the requirement of ISO 10993 series Standards	Contact level: blood path, indirect, limited contact (<24 hours). Conforms to the requirement of ISO 10993 series Standards	Same
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Difference comment 1

The subject device is similar to the predicate device. There are minor differences in needle length and dimension. These differences do not affect intended use. In addition, differences were addressed through ISO 7864 and ISO 9626. Therefore, the differences on models and the specification of needle length and needle width will not raise different question of safety and effectiveness.

Difference comment 2

The material of the needle of the subject device is similar to the predicated device. They are both stainless steels. The differences on materials do not raise new questions about safety and effectiveness.

Difference comment 3

The sterilization of the predicate device was unknown while the subject device was sterilized by EO to achieve a SAL of 10-6 and it has been validated to ISO11135. Both devices are sterile.

Discussion:

- From clinical aspect: The subject device has the same indication for use as the predicate.
- From technological aspect: The subject device has the same principle of operation, and configuration.
- From product performance. The main difference is that specification of models and the specification of needle length and needle width. However, all of them will be selected by health care provider per injection requirement and this difference does not affect indication for use. Additionally, the performance of needle has been evaluated and the test results met the requirements of ISO 7886-1 and ISO 7864. Therefore, this difference does not affect substantially equivalency on safety and effectiveness.
- From material perspective: The biocompatibility of the subject device was evaluated through tests according to the requirements of ISO10993 series standards. Therefore, this difference does not affect substantially equivalency on safety and effectiveness.

- From sterilization: The subject device was sterilized by EO to achieve a SAL of 10-6 and it has been validated to ISO11135. Therefore, this difference does not affect substantially equivalency 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 Bifurcated 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：

In Vitro Cytotoxicity Test	ISO 10993-5: 2009
Skin Sensitization Test	ISO 10993-10: 2010
In Vitro Hemolysis Test	ISO 10993-4: 2017
Intracutaneous Reactivity Test	ISO 10993-10: 2010
Acute Systemic Toxicity Test	ISO 10993-11: 2017
Pyrogen Test	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 testing is performed according to the following standards:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008

The shelf life of 5 year is determined based on stability studies which include ageing test according to FDA recognized standard ASTM F1980-16.

Package integrity testing was conducted on the final, packaged, and sterile devices after environmental conditioning and simulated transportation. All packaging deemed acceptable for protection of product and sterility maintenance.

The testing is performed according to the following standards:

Seal strength	ASTM F88/F88M-15
Blue Dye Penetration	ASTM F 1929-2015
Seal Integrity (Visual Inspection)	ASTM F 1886/ F 1886M-16

Performance testing

Performance testing is performed according to the following standards:

- ISO 7864: 2016, Sterile hypodermic syringes for single use
- ISO 9626:2016, Stainless Steel Needle Tubing For The Manufacture of Medical Devices-Requirements and test methods.

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The Bifurcated Needle IS substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.