August 24, 2021

Anhui Tiankang Medical Technology Co.,Ltd.
Bai Baodong
General Manager
No.228 Weiyi Road, Economic Development Zone
Tianchang, Anhui 239300
China

Re: K210464
Trade/Device Name: Auto Disable Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 23, 2021
Received: July 26, 2021

Dear Bai Baodong:

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,

For CAPT. Alan M. Stevens
Assistant Director Injection Devices Team 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)*
K210464

Device Name
AUTO DISABLE SYRINGE

Indications for Use *(Describe)*
The AUTO DISABLE SYRINGE is intended for use in the suction and injection of vaccine for medical purposes. Additionally , after injection to the body, the plunger can be automatically locked by the triggered mechanism to prevent the re-use of this syringe.

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.

K210464 510(K) Summary

Date prepared: August 24, 2021

Submitter Name and Address:

Submitter Name:	Anhui Tiankang Medical Technology Co., Ltd.
Address:	No.228 Weiyi Road, Economic Development Zone, Tianchang City. Anhui, China
Contact Person:	Bai Baodong, General Manager
TEL:	+86-550-7309187
FAX:	+86-550-7308901
E-mail:	tkquality@126.com

Submission Devices Information:

Trade/Proprietary Name: AUTO DISABLE SYRINGE
Classification name: Syringe, piston
Class: II.
Product codes: FMF
Regulation number: 21CFR880.5860,

Submission Type: 510(K)

Predicate Device Information:

Company Name: Becton, Dickinson, and Company

Device name: BD SoloShot Mini Syringe/ BD Auto Disable Syringe
510(K) Number: K201234

Device Description

1) Indication for use:

The AUTO DISABLE SYRINGE is intended for use in the suction and injection of vaccine for medical purposes. Additionally, after injection to the body, the plunger can be automatically locked by the triggered mechanism to prevent the re-use of this syringe.

2) Design of syringe:

The AUTO DISABLE SYRINGE is designed for the hypodermic injection of the intended micro

scale solution. It has the automatic function in the structure of the syringe which after injection of an intended fixed dose locks the syringe to prevent re-use of the syringe. It can be widely used for injection of vaccine for the immunization.

3) Structure of syringe (with needle):

The syringe consists of a calibrated hollow barrel, a movable plunger, a rubber stopper (piston) assembled at end of the plunger, and a steel clip installed between the barrel and the plunger that functions to prevent re-use of the syringe.

At the end of the barrel, a fixed an unmovable needle is installed, and a needle cap covers the needle. The zero line and nominal capacity line are printed outside of barrel. The main materials are PP, latex free (polyisoprene rubber) and stainless steel.

The AUTO DISABLE SYRNGE is for Prescription (Rx) use only

Product models:

Description	Needle Length
1cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
1cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
1cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
1cc(ml), with needle:26G	3/8” and 1/2”
1cc(ml), with needle:27G	3/8” and 1/2”
1cc(ml), with needle:28G	3/8” and 1/2”
1cc(ml), with needle:29G	3/8” and 1/2”
1cc(ml), with needle:30G	3/8” and 1/2”

Description	Needle Length
0.5cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.5cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.5cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.5cc(ml), with needle:26G	3/8” and 1/2”
0.5cc(ml), with needle:27G	3/8” and 1/2”
0.5cc(ml), with needle:28G	3/8” and 1/2”
0.5cc(ml), with needle:29G	3/8” and 1/2”
0.5cc(ml), with needle:30G	3/8” and 1/2”

Description	Needle Length
0.4cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.4cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.4cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.4cc(ml), with needle:26G	3/8” and 1/2”
0.4cc(ml), with needle:27G	3/8” and 1/2”
0.4cc(ml), with needle:28G	3/8” and 1/2”
0.4cc(ml), with needle:29G	3/8” and 1/2”
0.4cc(ml), with needle:30G	3/8” and 1/2”

Description	Needle Length
0.3cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.3cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.3cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.3cc(ml), with needle:26G	3/8” and 1/2”
0.3cc(ml), with needle:27G	3/8” and 1/2”
0.3cc(ml), with needle:28G	3/8” and 1/2”
0.3cc(ml), with needle:29G	3/8” and 1/2”
0.3cc(ml), with needle:30G	3/8” and 1/2”

Description	Needle Length
0.25cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.25cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.25cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.25cc(ml), with needle:26G	3/8” and 1/2”
0.25cc(ml), with needle:27G	3/8” and 1/2”
0.25cc(ml), with needle:28G	3/8” and 1/2”
0.25cc(ml), with needle:29G	3/8” and 1/2”
0.25cc(ml), with needle:30G	3/8” and 1/2”

Description	Needle Length
0.2cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.2cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.2cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.2cc(ml), with needle:26G	3/8” and 1/2”
0.2cc(ml), with needle:27G	3/8” and 1/2”
0.2cc(ml), with needle:28G	3/8” and 1/2”
0.2cc(ml), with needle:29G	3/8” and 1/2”
0.2cc(ml), with needle:30G	3/8” and 1/2”

Description	Needle Length
0.1cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.1cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.1cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.1cc(ml), with needle:26G	3/8” and 1/2”
0.1cc(ml), with needle:27G	3/8” and 1/2”
0.1cc(ml), with needle:28G	3/8” and 1/2”
0.1cc(ml), with needle:29G	3/8” and 1/2”
0.1cc(ml), with needle:30G	3/8” and 1/2”

Description	Needle Length
0.05cc(ml), with needle:23G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.05cc(ml), with needle:24G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.05cc(ml), with needle:25G	3/8”, 1/2”, 3/4”, 7/8”, 1”
0.05cc(ml), with needle:26G	3/8” and 1/2”
0.05cc(ml), with needle:27G	3/8” and 1/2”
0.05cc(ml), with needle:28G	3/8” and 1/2”
0.05cc(ml), with needle:29G	3/8” and 1/2”
0.05cc(ml), with needle:30G	3/8” and 1/2”

Comparison of technological characteristics with the predicate:

Elements of comparison	Subject device AUTO DISABLE SYRINGE	Predicate device: BD SoloShot Mini Syringe/ BD Auto Disable Syringe (K201234)	Comments
Indications for Use	The AUTO DISABLE SYRINGE is intended for use in the suction and injection of vaccine for medical purposes. Additionally, after injection to the body, the plunger can be automatically locked by the triggered mechanism to prevent the re-use of this syringe.	BD SoloShot Mini Syringe/ BD Auto Disable Syringe is intended for aspiration and injection of fluids.	Comment 1.
Principle of operation	Normal	Normal	Identical
Needle length	3/8", 1/2", 1"	3/8", 5/8", 3/4", 1"	Comment 2.
Needle gauge	23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	23G, 24G, 25G, 27G	Comment 3
Syringe capacity	0.05ml, 0.10ml, 0.20ml, 0.25ml, 0.30ml, 0.40ml, 0.50ml, 1.0ml	0.05ml, 0.10ml, 0.50ml,	Comment 4
Reuse Prevention (Safety) Feature	Auto-disabled, prevents syringe re-use	Auto-disabled, prevents syringe re-use	Identical
Lubricant for barrel	Silicone oil	Silicone oil	Identical
Barrel transparency	Transparent and clear	Transparent and clear	Identical
Gradations legibility	Legible	Legible	Identical

Material	Barrel: PP Plunger: PP Piston: Latex Free (Polyisoprene Rubber) Needle: stainless steel	Barrel: PP Plunger: PP Piston: rubber Needle: stainless steel	Comment 5
Performance	Conform to ISO7886-3 and ISO7886-1, ISO9629, ISO7864	Conform to ISO7886-3 and ISO7886-1, ISO9629, ISO7864	Identical
Biocompatibility	Conform to ISO10993	Conform to ISO10993	Identical
Labeling	Meet the requirements of 21CFR Part 801	Meet the requirements of 21CFR Part 801	Identical
Sterility	EO sterilization 10^{-6}	EO sterilization 10^{-6}	Identical

Discussions of differences in technological characteristics

Comment 1:

The indications for use are similar for both devices (to the extent that both devices are intended for aspiration and injection of fluids for medical purposes). The predicate device defines that the device is for general use. The subject device is specifically used for vaccine administration, which is included in the scope of general use. In addition, the subject device includes a statement regarding the locking mechanism to prevent re-use. This mechanism is included in the predicate design, but is not included in the indications for use statement. The differences to the indications for use statement between the predicate and the subject device are acceptable.

Comment 2, 3 and 4:

The specifications of the proposed device and predicate device are different; however, both of them comply with the same recognized standards. The different sizes of needle are addressed through performance testing.

Comment 5:

The piston used the new technology material to replace the traditional rubber material for less toxicity (Polyisoprene Rubber). The safety testing report of biocompatibility and function performance testing report demonstrates that the change does not negatively impact safety and performance.

Non-Clinical Testing

Functional Performance Testing

The AUTO DISABLE SYRINGE described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

ISO 7864:2016, Sterile hypodermic needles for single use - Requirements and test methods

- Fragmentation test
- Determination of flow rate
- Lubricant: Penetration force and drag force
- Bonding strength

ISO 7886-3, sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization and ISO7886-1, sterile hypodermic syringes for single use - Part 1: Syringes for manual use

- Limits for acidity and alkalinity
- Limits for extractable metals
- Lubricant: Penetration force and drag force
- Tolerance on nominal capacity
- Graduated scale
- Barrel- dimensions and flanges
- Plunger stopper and assembly – fitness of stopper /plunger in barrel
- Integrated needle
- Sharps protection features
- Dead space
- Freedom from air and liquid leakage
- Auto-disable syringe feature

ISO9626, Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods

- Limits for acidity and alkalinity
- designated metric size
- Stiffness
- Resistance to breakage
- Resistance to corrosion

Sterility, Shipping and Shelf-Life

- EO sterilization validation and package validation conducted in accordance with ISO11135:2014, ISO11607-1:2019, ISO11607:2019

- Sterilant residuals were evaluated per ISO10993-7:2008. Average daily dose to patient of EO less than 4mg/device and ECH less than 9mg/device
- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ASTM D4169-16, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.
- Sterile Barrier Packaging Testing performed on the proposed device:
    - Seal strength ASTM F88/F88-15
    - Visual Inspection ASTM F 1886-16
    - Dye penetration ASTM F1929-15
- Shelf life of 5 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Biocompatibility Testing (ISO10993-1:2018)

In accordance with ISO 10993-1, the syringe is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours). The following testing was conducted:

- Cytotoxicity (per ISO10993-5:2009)
- Sensitization (per ISO10993-10:2014)
- Irritation (per ISO10993-10:2017)
- Acute Systemic Toxicity (per ISO10993-11:2017)
- Pyrogenicity (per ISO10993-4:2017)
- Hemocompatibility (per ISO10993-4:2017)
- Particulate matter (per USP<788>)

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The AUTO DISABLE SYRINGE is substantially equivalent to BD SoloShot Mini Syringe/ BD Auto Disable Syringe with respect to the indications for use and technological characteristics.