



January 4, 2024

Ningbo Medsun Medical Co., Ltd.
Liu Ping
Regulation Affairs Manager
No.55 Jinxi Road, Zhenhai, Ningbo, Zhejiang 315221 China

Re: K232330
Trade/Device Name: Lancing System
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK, QRL
Dated: July 21, 2023
Received: August 3, 2023

Dear Liu Ping:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark
Trumbore -S

Digitally signed by
Mark Trumbore -S
Date: 2024.01.04
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Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K232330

Device Name

Lancing System

Indications for Use (Describe)

Lancet:

Lancet is intended to be used to obtain capillary blood sample for self-monitoring of blood glucose.

Lancing Device:

Lancing Device is used with lancets to draw a capillary blood sample for testing, utilizing small amounts of blood. The

Lancing Device is intended for use by a single patient and should not be shared.

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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510(k) Summary

1.Date Prepared: July 21th, 2023

2.Submitter

Ningbo Medsun Medical Co., Ltd.

No.55 Jinxi Road, Zhenhai, 315221, Ningbo, P.R.China

Contact Person: Liu Ping, Regulation Affairs Manager

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Consultant: Marvin Li

Date Prepared: July 21th, 2023

3.Device

Trade Name: Lancing System

Common Name:Blood Lancets

Classification Name: Multiple Use Blood Lancet For Single Patient Use Only

Regulation Number:21 CFR 8780.4850

Regulatory Class: II

Product Code: QRK, QRL

Review Panel: General & Plastic Surgery

4.Predicate device

Manufacturer: Tianjin Huahong Technology Co., Ltd.

Device name: Lancet, Lancing device

510(k) number: K220475

5.Device description

Lance Device have two parts, lancet and lancing device. Lancet is composed of a lancet body, a needle and a protective cap. Lancing device is mainly composed of depth adjustment tip, cap, release button, shield, rear sliding barrel and an ejector. The cover consists of inner cover, cap inner core, rear sliding barrel, inner core, buckle ring and two springs, with 12 depth adjustment gears.

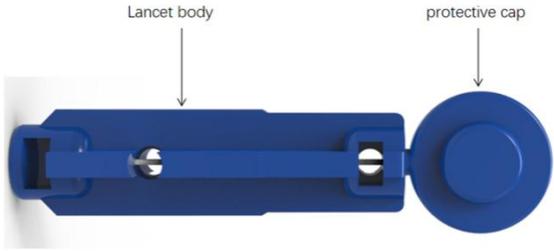
The lancet is provided as sterile state and have four model: Model BYY3, Model BYY4,

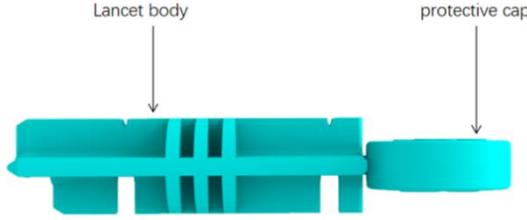
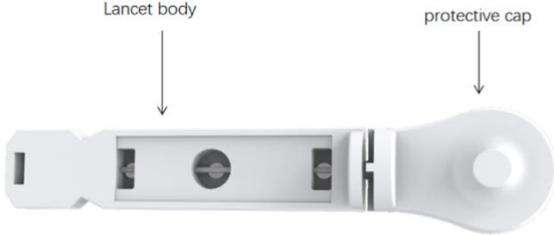
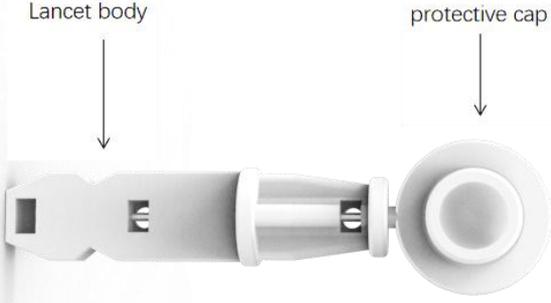
Model BYB and Model BYC. The lancet body of Model BYY3 and Model BYY4 is circular, and the lancet body of Model BYB and Model BYC is flat. The lancing device is provided as non-sterile state and a reusable medical device for use only on a single patient and have four model: Model CX11B1, Model CX11B2, Model CX11C1 and Model CX11C2. Model CX11 Lancing device is divided into CX11B (threaded connection) and CX11C (buckle connection) according to the different connection structures of the cap and body of the lancing device. Model CX11B is divided into CX11B1 (suitable for round lancet) and CX11B2 (suitable for flat lancet) according to the different structure of the lancet. Model CX11C is divided into CX11C1 (suitable for round lancet) and CX11C2 (suitable for flat lancet) according to the different structures of the lancet.

The lancet is sterilized by Gamma ray and for single use, the shelf life is 5 years. The lancing device is provided as non-sterile state, for use only on a single patient. The useful life is 5 years or 6000 times.

Product Structure of the Lancing System are summarized in the table below:

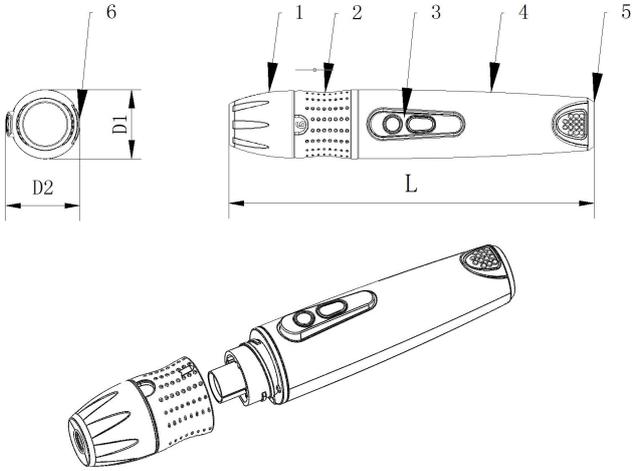
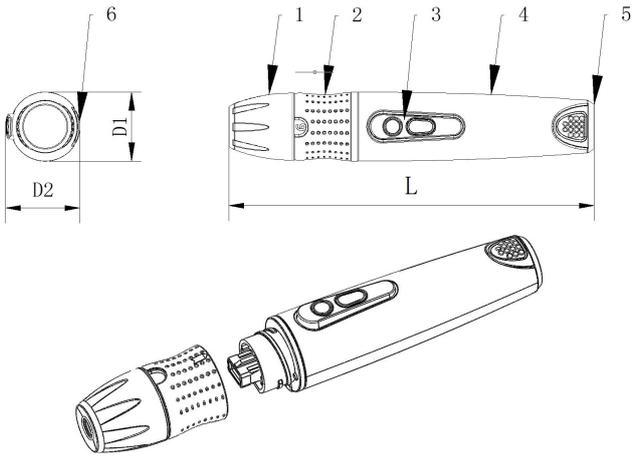
5.1 Lancet

Model	Design features
<p>Model BYY3</p>	<p>Model BYY3 Lancet is composed of a lancet body, a needle and a protective cap. The needle is fully enclosed by the protective cap. The lancet is colour coded for different versions. The structure of the lancet is circular.</p> <p><u>Parts and components of Model BYY3:</u></p> 
<p>Model BYY4</p>	<p>Model BYY4 Lancet is composed of a lancet body, a needle and a protective cap. The needle is fully enclosed by the protective cap. The lancet is colour coded for different versions. The structure of the lancet is circular.</p> <p><u>Parts and components of Model BYY4:</u></p>

	
<p>Model BYB</p>	<p>Model BYB Lancet is composed of a lancet body, a needle and a protective cap. The needle is fully enclosed by the protective cap. The lancet is colour coded for different versions. The structure of the lancet is flat.</p> <p><u>Parts and components of Model BYB:</u></p> 
<p>Model BYC</p>	<p>Model BYB Lancet is composed of a lancet body, a needle and a protective cap. The needle is fully enclosed by the protective cap. The lancet is colour coded for different versions. The structure of the lancet is flat.</p> <p><u>Parts and components of Model BYB:</u></p> 

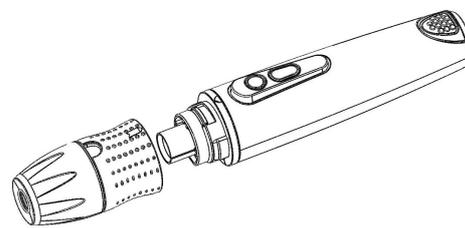
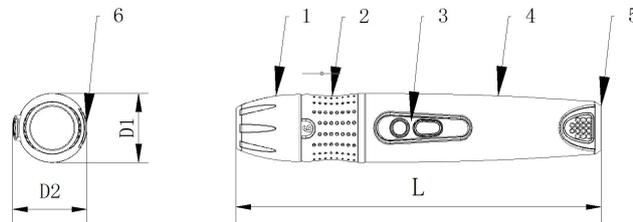
5.2 Lancing Device

Model	Design features
<p>Model CX11B1</p>	<p>Model CX11B1 Lancing device is mainly composed of a depth adjustment tip, a cap, a release button, a shield, a rear sliding barrel and an ejector. The cover consists of an inner cover, a cap inner core, a rear sliding barrel, an inner core, a buckle ring, and two springs, with 12 depth adjustment gears. Model CX11B1 Lancing device is connected with thread. Model CX11B1 Lancing device will be compatible with Model BYY3 and Model BYY4</p>

	<p>Lancet(round lancet).</p> <p><u>Parts and components of Model CX11B1:</u></p>  <p>1-Adjustable Tip; 2-Cap; 3-Release Button; 4-Shield; 5-Rear Sliding Barrel; 6-Ejector</p>
<p>Model CX11B2</p>	<p>Model CX11B2 Lancing device is mainly composed of a depth adjustment tip, a cap, a release button, a shield, a rear sliding barrel and an ejector. The cover consists of an inner cover, a cap inner core, a rear sliding barrel, an inner core, a buckle ring, and two springs, with 12 depth adjustment gears. Model CX11B2 Lancing device is connected with thread. Model CX11B2 Lancing device will be compatible with Model BYB and Model BYC Lancet(flat lancet).</p> <p><u>Parts and components of Model CX11B2:</u></p>  <p>1-Adjustable Tip; 2-Cap; 3-Release Button; 4-Shield; 5-Rear Sliding Barrel; 6-Ejector</p>
<p>Model CX11C1</p>	<p>Model CX11C1 Lancing device is mainly composed of a depth adjustment tip, a cap, a release button, a shield, a rear sliding barrel and an ejector. The cover consists of an inner cover, a cap inner core, a rear sliding barrel, an</p>

inner core, a buckle ring, and two springs, with 12 depth adjustment gears. Model CX11C1 Lancing device is connected with buckle. Model CX11C1 Lancing device will be compatible with Model BYY3 and Model BYY4 Lancet(round lancet).

Parts and components of Model CX11C1:

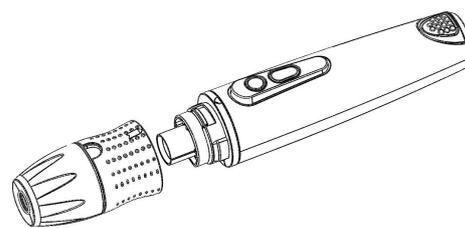
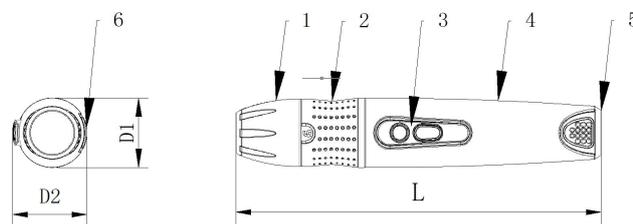


1-Adjustable Tip; 2-Cap; 3-Release Button;
4-Shield; 5-Rear Sliding Barrel; 6-Ejector

Model
CX11C2

Model CX11C2 Lancing device is mainly composed of a depth adjustment tip, a cap, a release button, a shield, a rear sliding barrel and an ejector. The cover consists of an inner cover, a cap inner core, a rear sliding barrel, an inner core, a buckle ring, and two springs, with 12 depth adjustment gears. Model CX11C2 Lancing device is connected with buckle. Model CX11C2 Lancing device will be compatible with Model BYB and Model BYC Lancet(flat lancet).

Parts and components of Model CX11C2:



1-Adjustable Tip; 2-Cap; 3-Release Button;
4-Shield; 5-Rear Sliding Barrel; 6-Ejector

6. Indications for use

Lancet is intended to be used to obtain capillary blood sample for self-monitoring of blood glucose.

Lancing Device is used with lancets to draw a capillary blood sample for testing, utilizing small amounts of blood. The Lancing Device is intended for use by a single patient and should not be shared.

7. Comparison of technological characteristics with the predicate device

The comparison and discussion between the subject device and the predicate devices are listed in below table 1 and 2.

Description	Subject Device	Predicate Devices (K220475)	Remark
Proprietary/trade name	Lancet	Lancet	Same
Product Code	QRK, QRL	QRK, QRL	Same
Regulation Number	21CFR 8780.4850	21CFR 8780.4850	Same
Class	II	II	Same
Indications for use	Lancet is intended to be used to obtain capillary blood sample for self-monitoring of blood glucose.	It is intended for capillary blood sampling.	Same
Prescription/over-the counter use	Over-the counter use	Over-the counter use	Same
Applicable user	Lay users	Healthcare professional or lay person	Different (Note 1)
Reuse or single use	Single use	Single use	Same
Sterilization method and SAL	Irradiation Sterilization SAL:10 ⁻⁶	Irradiation Sterilization SAL:10 ⁻⁶	Same
Shelf-life	5 years	5 years	Same
Design and	For the Lancet,	For the Lancet,	Same

Manufacturing	stainless steel needle is fed into an injection molding machine to over-mold plastic material (polyethylene (PE)) forming a body and cap, encapsulating the stainless steel.The Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	stainless steel needle is fed into an injection molding machine to over-mold plastic material(polyethylene (PE) and Ethylene Vinyl Acetate (EVA) and calcium powder) forming a body and cap, encapsulating the stainless steel. The Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	
Needle length range	3.3±0.5mm	3.2±0.3mm (Model: IA、IB、IC、ID、IE、IK、IL、IM、IIA、IIB、III、VI) 2.1±0.3mm (Model:V)	Different (Note 2)
Gauge range	28G,29G,30G, 31G,32G,33G	1.50±0.02mm (16G) 1.20±0.01mm (18G) 1.07±0.01mm (19G) 0.91±0.01mm (20G) 0.82±0.01mm (21G) 0.72±0.01mm (22G) 0.64±0.01mm (23G) 0.57±0.01mm (24G) 0.51±0.01mm (25G) 0.46±0.01mm (26G) 0.41±0.01mm (27G) 0.36±0.01mm (28G) 0.34±0.01mm (29G) 0.31±0.01mm (30G) 0.26±0.01mm (31G) 0.24±0.01mm (32G) 0.21±0.01mm (33G) 0.19±0.01mm (34G)	Different (Note 3)
Materials of parts in contact with human body	The Lancet has a needle that is made of stainless steel and silicone oil. The body	The Lancet has a needle that is made of stainless steel and silicone oil.	Different (Note 4)

	and cap are made of polyethylene (PE).	The body and cap are made of polyethylene (PE) and Ethylene Vinyl Acetate (EVA)	
Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Same

Table 1-General Comparison of Lancet

Note 1: The applicable user of the predicate device has both healthcare professional and lay person, but the applicable user of the subject device only has lay users.

Note 2: The needle length range of the predicate device has two dimensions, $3.2\pm 0.3\text{mm}$ and $2.1\pm 0.3\text{mm}$, but the needle length range of the subject device only has one dimension, $3.3\pm 0.5\text{mm}$. Although the dimension is different, the puncture depth may be adjusted through the lancing device when the subject device is used. The difference will not effect the safety and effectiveness of the subject device.

Note 3: The gauge range of the predicate device has 18 types, but the gauge range of the subject device only has 6 types. All of the gauge range are referred to ISO 9626:2016.

Note 4: The materials of parts in contact with human body of the predicate device are stainless steel, silicone oil, PE and EVA, but the materials of parts in contact with human body of the subject device are stainless steel, silicone oil and PE. The safety of materials of the subject device have been certified by biocompatibility test.

Description	Subject Device	Predicate Devices (K220475)	Remark
Proprietary/trade name	Lancing Device	Lancing Device	Same
Product Code	QRK,QRL	QRK,QRL	Same
Regulation Number	21CFR 8780.4850	21CFR 8780.4850	Same
Class	II	II	Same

Indications for use	Lancing Device is used with lancets to draw a capillary blood sample for testing, utilizing small amounts of blood. The Lancing Device is intended for use by a single patient and should not be shared.	The Lancing Device is used with lancets to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared.	Same
Prescription/over-the counter use	Over-the counter use	Over-the counter use	Same
Puncture device to obtain micro blood samples	Yes	Yes	Same
Lancet retracted after use to prevent sharp injure	Yes	Yes	Same
Device penetration depth range	0~1.8mm±0.5mm	0.85mm(0.30mm)~2.20mm(±0.30mm) (Model: HH-X-T); 0.60mm(0.30mm)~2.00mm(±0.30mm) (Model HH-XIII-T、HH-XXII-T); 0.50mm(0.30mm)~1.70mm(±0.30mm) (Model HH-XV-T); 0.60mm(0.30mm)~1.95mm(±0.30mm) (Model HH-XVI-T、HH-XXI-T、HH-XXIII-T、HH-XXIV-T); 0.60mm(0.30mm)~1.80mm(±0.30mm) (Model HH-XVII-T、HH-XIX); 0.60mm(0.30mm)~2.10mm(±0.30mm) (Model HH-XVIII-T)	Different (Note 5)
Mechanical loading and firing function	Cocking barrel with releasing button	Cocking barrel with releasing button	Same

Reuse or single use	.Reuse,for use only on a single patient.	Reusable,Single Patient Use Only	Same
Sterilization method and SAL	N/A	N/A	Same
Materials	ABS, POM and PC Resin	ABS, POM and PC Resin	Same
Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Unknown	Different (Note 6)

Table 2-General Comparison of Lancing device

Note 5: The device penetration depth range of the predicate device has different dimensions for different models. The device penetration depth range of the subject device also has different dimensions,the max range is $1.8\text{mm} \pm 0.5\text{mm}$ for each model of subject device, which can be turned 12 kinds different penetration depth range from 0- $1.8\text{mm} \pm 0.5\text{mm}$ for patient. It will reduce the pain of puncture when the appropriate gear is selected.

Note 6: The biocompatibility of predicate device is unknown. The biocompatibility of the subject device is met the ISO 10993 series standards.

8.Performance testing summary

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

8.1Biocompatibility testing

Per FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued on September 4, 2020. The biocompatibility evaluation items of proposed device were completed.

The testing of lancet included the following tests:

- In vitro cytotoxicity
- Skin sensitization

- Intracutaneous reactivity
- Acute systemic toxicity
- Pyrogen

The testing of lancing device included the following tests:

- In vitro cytotoxicity
- Skin sensitization
- Skin Irritation

8.2 Performance testing-Bench

Lancet with sterilization had been tested. The test items mainly include the following contents.

- Appearance
- Dimension
- Needle-tip
- Puncture force
- Connecting fastness
- Corrosion resistance feature
- Limits for acidity and alkalinity
- Total heavy metal content and Cd content
- Sealing strength
- Sterile barrier integrity
- Sterility

Lancing device had been tested. The test items mainly include the following contents.

- Appearance
- Dimension
- Compatibility
- Coaxiality
- Depth adjustment
- Packages and Labels
- Drop test
- Needle unloading thrust

- Torque test(for model CX11B1 and CX11B2)
- Buckle force(for model CX11C1 and CX11C2)
- Separating force(for model CX11C1 and CX11C2)

8.3 Compatibility between lancet with lancing device

The compatibility between lancet with lancing device have been studied. The results show that the different model lancet is well compatibility the corresponding model lancing device. The information is as the follow and printed on the label:

Lancet	Compatible Lancing Device
Model BYY3	Model CX11B1,CX11C1
Model BYY4	Model CX11B1,CX11C1
Model BYB	Model CX11B2,CX11C2
Model BYC	Model CX11B2,CX11C2

8.4 Clinical simulated use testing

Beside, according to 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 and Guidance for Industry and FDA Staff-Medical Devices with Sharps Injury Prevention Features, we have completed the test of clinical simulated use testing for sharps injury protection of lancing system. The test results show that the product had well sharps injury prevention feature.

9. Conclusions

Based on device comparison information and non-clinical bench testing, the subject device is substantially equivalent to the predicate devices (K220475).