June 3, 2022

Guangzhou Shengwei Medical Devices Co., Ltd
Xiaojun Cai
Marketing Manager
No. 126, Guangshao Road, Aotou Town
Conghua city, Guangdong 510900
China

Re: K214063
Trade/Device Name: Model 121 Biopsy Needle, Model 111 Biopsy Needle, Model 112 Biopsy Needle, and Model 131 Disposable Coaxial Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: December 24, 2021
Received: December 27, 2021

Dear Xiaojun Cai:

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,

Long Chen, 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

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)*
K214063

Device Name
Model 121 Biopsy Needle, Model 111/112 Biopsy Needle, and Model 131 Disposable Coaxial Biopsy Needle

Indications for Use *(Describe)*
The Shengwei Biopsy needle consist of Model 121 Biopsy Needle, Model 111/112 Biopsy Needle, and Model 131 Disposable Coaxial Biopsy Needle. These devices are indicated for use as follows:

- Model 121 Biopsy Needle is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.

- Model 111/112 Biopsy Needle is intended for obtaining core biopsy from samples soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone.

Model 111/112 Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the abnormality.

- Model 131 Disposable Coaxial Biopsy Needle is intended for use with biopsy needle during soft tissue core biopsy procedures. The device is not intended for use in bone.

The extent of histological abnormality cannot be reliably determined from it mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

Guangzhou Shengwei Medical Devices Co., Ltd
No. 126, Guangshao Road, Aotou Town, Conghua city, Guangzhou, China .
Phone: +86-13660308085
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Primary Contact Person:	Xiaojun Cai Marketing Manager Guangzhou Shengwei Medical Devices Co., Ltd Tel: (+86) -13660308085 Fax: (+86) - 020-87886883
Date prepared	December 24, 2021

2. DEVICE

Device Name:	Biopsy Needle
Common name:	Biopsy Needle
Regulation number	21 CFR 876.1075
Regulation Class:	Class II
Product Code:	KNW FCG

3. PREDICATE DEVICE

K853312 ARGON CUT BIOPSY NEEDLES, VARIOUS SIZES

K133948 BARD(R) MAX-CORE(R) DISPOSABLE CORE INSTRUMENT

K160316, Biopsy Devices and Accessories

The predicate devices K133948 and K160316 had been subject to a non-design related recall.

4. DEVICE DESCRIPTION

The Shengwei Biopsy needle include semi-automatic and automatic spring powered guns (disposable). Cannula accessory is provided in a variety of sizes, designed to work with the manufacturer's semi-automatic and automatic guns to obtain and deliver a soft tissue core sample, facilitate skin and tissue penetration, sample retention and / or expulsion depending on the sample sites. The following biopsy devices are included

in this submission for Shengwei Biopsy needle [Table 1].

Table 1 Soft Tissue Biopsy Devices and Accessories

Product Name	Product Description
Biopsy Devices	
Model 111	Disposable, automatic device for core biopsy of soft tissue
Model 112	Disposable, automatic device for core biopsy of soft tissue with locking function.
Model 121	Disposable, semi-automatic device for core biopsy of soft tissue
Biopsy Device Accessories: Disposable Coaxial Biopsy Needle	
Model 131	Disposable needles for introduction of cannula, or biopsy devices

4.1 **Device Format**

The device format consists of two configurations: individually packaged sterile devices, co-packaged with various sterile compatible introducer needles in disposable packaging materials in various sized medical grade plastic blister pouches. These devices includes automatic guns (disposable design) packaged individually, or provided with compatible needles. The packaging is compatible with the product's EO sterilization method.

5. INDICATIONS FOR USE

The Shengwei Biopsy needle consist of Model 121 Biopsy Needle, Model 111/112 Disposable Biopsy Needle, and Model 131 Disposable Coaxial Biopsy Needle. These devices are indicated for use as follows:

- **Model 121 Biopsy Needle** is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.

- **Model 111/112 Biopsy Needle** is intended for obtaining core biopsy from samples soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone.

  Model 111/112 Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the abnormality.

- **Model 131 Disposable Coaxial Biopsy Needle** is intended for use with biopsy needle during soft tissue core biopsy procedures. The device is not intended for use in bone.

  The extent of histological abnormality cannot be reliably determined

from it mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is the same as the predicate device in the intended use, material, biocompatibility, and similar in product style, design feature and dimension. So the subject device is similar to the predicate device.

Table 2: Comparison of the Model 111 Biopsy Needle to the predicate device.

	Subject Device	Predicate Device (K160316)	Predicate Device (K133948)	Comments
Trade Name	Model 111 Biopsy Needle	Themy Automatic Disposable Biopsy Device	BARD(R) MAX-CORE(R) DISPOSABLE CORE INSTRUMENT	
Manufacturer	Guangzhou Shengwei Medical Devices Co., Ltd	M.D.L. S.r.l.	BARD PERIPHERAL VASCULAR, INC	
Device Class	Class II	Class II	Class II	Same
Product Code	KNW,FCG	KNW,FCG	KNW	Same
Regulation number	876.1075	876.1075	876.1075	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Device Description	Disposable programmable automatic spring- loaded guillotine style biopsy system for histological biopsy on soft tissue.	Disposable programmable automatic spring- loaded guillotine style biopsy system for histological biopsy on soft tissue.	Disposable programmable automatic spring- loaded guillotine style biopsy system for histological biopsy on soft tissue.	Same
Intended Use/ Indications for Use Use/ Indications for Use	Model 111 Biopsy Needle is intended for obtaining core biopsy samples from soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone. Model 111 Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial	Themy Automatic Biopsy Needle is intended for obtaining core biopsy samples from soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone. Themy Automatic Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or	The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue masses. It is not intended for use in bone.	Same

	or complete removal of the abnormality.	complete removal of the abnormality.		
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Mechanics of Operation	Single hand automatic activation	Single hand automatic activation	Single hand automatic activation	Same
Gauge	14G-20G	14G-20G	14G-20G	Same
Needle Length	100mm-250mm	100 mm to 300 mm	100 mm to 250 mm	Same
Patient/ Tissue Contact Material	Inner needle and outer needle are made out of 304 stainless steel (X5CrNi18-9).Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Same
Performance	Complied with ISO 9626	Complied with ISO 9626	Complied with ISO 9626	Same
Sterilization	EO Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Yes	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

Table 3: Comparison of the Model 112 Biopsy Needle to the predicate device.

	Subject Device	Predicate Device (K160316)	Predicate Device (K133948)	Comments
Trade Name	Model 112 Biopsy Needle	Themy Automatic Disposable Biopsy Device	BARD(R) MAX-CORE(R) DISPOSABLE CORE INSTRUMENT	
Manufacturer	Guangzhou Shengwei Medical Devices Co., Ltd	M.D.L. S.r.l.	BARD PERIPHERAL VASCULAR, INC	
Device Class	Class II	Class II	Class II	Same
Product Code	KNW,FCG	KNW,FCG	KNW	Same
Regulation number	876.1075	876.1075	876.1075	Same
Regulation Name	Gastroenterology- Urology Biopsy Instrument	Gastroenterology- Urology Biopsy Instrument	Gastroenterology- Urology Biopsy Instrument	Same
Device Description	Disposable programmable automatic spring- loaded guillotine style biopsy system for histological biopsy on soft tissue.	Disposable programmable automatic spring- loaded guillotine style biopsy system for histological biopsy on soft tissue.	Disposable programmable automatic spring- loaded guillotine style biopsy system for histological biopsy on soft tissue.	Similar It has an insurance mechanism to prevent accidental activation before

				puncture
Intended Use/ Indications for Use Use/ Indications for Use	Model 112 Biopsy Needle is intended for obtaining core biopsy samples from soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone. Model 112 Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the abnormality.	Themy Automatic Biopsy Needle is intended for obtaining core biopsy samples from soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone. Themy Automatic Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the abnormality.	The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue masses. It is not intended for use in bone.	Same
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Mechanics of Operation	Single hand automatic activation	Single hand automatic activation	Single hand automatic activation	Same
Gauge	14G-20G	14G-20G	14G-20G	Same
Needle Length	100mm-250mm	100 mm to 300 mm	100 mm to 250 mm	Same
Patient/Tissue Contact Material	Inner needle and outer needle are made out of 304 stainless steel (X5CrNi18-9). Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Same
Performance	Complied with ISO 9626	Complied with ISO 9626	Complied with ISO 9626	Same
Sterilization	EO Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Yes	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

Table 4: Comparison of the Model 121 Biopsy Needle to the predicate device.

	Subject Device	Predicate Device (K160316)	Predicate Device (K853312)	Comments
Trade Name	Model 121 Biopsy Needle	SemiCut Semi-Automatic Biopsy Needle	ARGON CUT BIOPSY NEEDLES, VARIOUS SIZES	
Manufacturer	Guangzhou Shengwei Medical Devices Co., Ltd	M.D.L. S.r.l.	ARGON MEDICAL CORP	
Device Class	Class II	Class II	Class II	Same
Product Code	KNW,FCG	KNW,FCG	DWO	Same
Regulation number	876.1075	876.1075	478.4800	Same
Regulation Name	Gastroenterology- Urology Biopsy Instrument	Gastroenterology- Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Device Description	Disposable semi- automatic spring loaded guillotine style biopsy system with adjustable penetration depth for histological biopsy on soft tissue.	Disposable semi- automatic spring loaded guillotine style biopsy system with adjustable penetration depth for histological biopsy on soft tissue.	Disposable semi-automatic spring loaded guillotine style biopsy system with adjustable penetration depth for histological biopsy on soft tissue.	Same
Intended Use/ Indications for Use Use/ Indications for Use	intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.	intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.	intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.	Same
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Mechanics of Operation	Single hand automatic activation	Single hand automatic activation	Single hand automatic activation	Same
Gauge	14G-20G	14G-20G	14G-20G	Same
Needle Length	100mm-250mm	70 mm to 300 mm	90 mm to 200 mm	Similar, the difference does not cause any safety and effectiveness concern.
Patient/Tissue Contact Material	Inner needle and outer needle are made out of 304 stainless steel (X5CrNi18-9). Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the	Same

			patient.	
Performance	Complied with ISO 9626	Complied with ISO 9626	Complied with ISO 9626	Same
Sterilization	EO Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Yes	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

Table 5: Comparison of the Model 131 Disposable Coaxial Biopsy Needle to the predicate device.

	Subject Device	Predicate Device (K160316)	Predicate Device (K853312)	Comments
Trade Name	Model 131 Disposable Coaxial Biopsy Needle	INTRO Coaxial Introducer Needles	ARGON CUT BIOPSY NEEDLES, VARIOUS SIZES	
Manufacturer	Guangzhou Shengwei Medical Devices Co., Ltd	M.D.L. S.r.l.	ARGON MEDICAL CORP	
Device Class	Class II	Class II	Class II	Same
Product Code	KNW,FCG	KNW,FCG	DWO	Same
Regulation number	876.1075	876.1075	478.4800	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Intended Use/ Indications for Use	Intended for use with biopsy devices cannula during soft tissue core biopsy procedures. The device is not intended for use in bone.	Intended for use with biopsy devices cannula during soft tissue core biopsy procedures. The device is not intended for use in bone.	Intended for use with biopsy devices cannula during soft tissue core biopsy procedures. The device is not intended for use in bone.	Same
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Gauge	15G-19G	13G-19G	13G-19G	Same
Needle Length	47mm-198mm	44 mm to 244 mm	35 mm to 151 mm	Similar, the difference does not cause any safety and effectiveness concern.
Device Type	Trocar tip stylet	Trocar tip stylet	Trocar tip stylet	Same
Visualization Technique	Conventional imaging guidance equipment excluding MRI	Conventional imaging guidance equipment excluding MRI	Conventional imaging guidance equipment excluding MRI	Same
Needle Material	Stainless steel	Stainless steel	Stainless steel	Same
Performance	Complied with ISO 9626	Complied with ISO 9626	Complied with ISO 9626	Same

Sterilization	EO Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Yes	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

7. PERFORMANCE DATA

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

Biocompatibility testing

The biocompatibility evaluation for the medical face mask was conducted in accordance with the International Standard ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity - (ISO 10993-5: 2009)
- Sensitization - (ISO 10993-10:2010)
- Skin Irritation - (ISO 10993-10:2010)
- Acute Systemic Toxicity-(ISO 10993-11:2017)
- Hemolysis-(ISO 10993-4:2017).

The devices met the requirements for non-pyrogenicity per Pyrogen Test USP<151>, Bacterial Endotoxins Test USP<85>. Sterilization was validated per ISO11135, and residuals for ETO, EG and ECH met ISO10993-7.

Device Shelf-life

The subject devices in their packaging were subjected to accelerated aging to simulate a 5 year shelf life (Treatment: 60°C, 28 days, <50% RH). Three lots of aged and non-aged subject devices were tested in triplicate for Mechanical Durability, Depth Projection, Device Needle Penetration, Activation Force (Spring Force) and Extraction to assess the impact of simulated aging on the device performance. Visual Appearance inspection for Metal Oxidation, Plastic Coloration, Plastic Integrity (cracks, damage) indicated that there no aesthetic, or design changes for the aged devices. Performance testing results of the aged devices was unchanged compared to untreated (non-aged) device.

Performance testing

Samples of each device product family (subject device) were selected at the extremes of device design for needle length and gauge sizes for comparative testing to predicate devices for device performance.

Depth Projection: Subject devices vs. predicate devices testing for Depth Projection measured the needle advancement during activation. Cannula needle advancement must meet a distance of ⩾ 20mm compared to the notch. The results showed that subject devices tested side-by-side with predicate devices were comparable over 50 shots per use and met criteria: Needle Advancement > 20 mm.

Penetration Force: Subject devices vs. predicate devices for Penetration Force was assessed using ASTM F3014 guidance. Simulation of biological tissues using a certified testing foil was used in the Dynamometer setup. Each tested subject and predicate device was activated 50 times to replicate the maximum number of biopsy shots performed during a medical procedure. The results showed that the subject devices required less force compared to the predicate devices and met the criteria: Penetration Force (Shengwei) < F (Predicate).

Activation Force: Subject and predicate device testing for Spring Force was measured during device activation. The results showed the subject devices tested side-by-side with predicate devices were comparable over 50 shots per use and met criteria: Spring Force (Shengwei) > F Predicate.

Mechanical Durability: Subject and predicate device testing for Mechanical Durability was performed in two parts: breaking force and detachment force. Device cannulas subjected to progressive force determined the breaking force. The detachment force test determined the point at which the plastic components sever from the device point of attachment. Results showed that subject devices in comparison to the predicate device met the criteria, Breakage Force (Shengwei) > F (Predicate), and Detachment of Components: Does Not Occur.

Extraction Testing: Subject and predicate devices testing for Sample Extraction quantitatively evaluated extraction capacity of subject devices compared with predicate devices. The results showed that the subject devices tested side-by-side with predicate devices were comparable over 50 shots per use compared to the predicate device. Model 111/112/121 devices produced slightly larger samples by weight compared to predicate device at 50 shots per use.

Table 6 Performance Testing Summary

Performance Testing	Device Name		
	Model 111	**Model 112**	**Model 121**
Biocompatibility per ISO10993	Meets	Meets	Meets
Pyrogen Test USP per <151> **Bacterial Endotoxins Test USP per <85>**	Meets	Meets	Meets
Residual ETO, ECH§, EG§ per ISO10993-7	Meets	Meets	Meets
Sterile per ISO 11135	Meets	Meets	Meets
Mechanism Performance			
• **Depth Projection** (1)	Similar**	N/A	Similar
• **Mechanical - Durability** (2)	Similar	Similar	Similar
• **Penetration** (3)	(a)	Pass	Pass
• **Activation Force (Spring)** (4)	Pass**	Pass	Pass
• **Extraction** (5)	***	***	***

** 20 mm Slot, ***Statistically Sig. Diff. (Shengwei Sample Wt. > Predicate Sample Wt.)

§ Below limit of quantitation (1 mg/device)

N/A/ not applicable (design), (a) Same Needle as Model 121.

Criteria: (1) Cannula Advancement > 20 mm = Pass; (2) Breakage Force (SHENGWEI) > FPredicate and Detachment of Components does not occur; (3) Penetration Force (SHENGWEI) < FPredicate; (4) Activation Force (Shengwei) < FPredicate; (5) Shengwei Non-statistically Significant Different to Predicate

8. CLINICAL DATA

No clinical data was included in this submission.

9. CONCLUSION

The indications for use statement for the subject device is similar to that of the predicate. The differences between the biopsy needle and its predicate device do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the medical face mask should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing described, Guangzhou Shengwei Medical Devices Co., Ltd concludes that the biopsy needle is as safe, as effective, and performs as well as or better than the legally marketed as the predicate devices (K853312, K133948, K160316).