January 29, 2020

Ushare Medical Inc.
℅ Raymond Luo
Technical Manager
Shanghai Sungo Management Consulting Co., Ltd.
13th F, 1500# Century Avenue
Shanghai, China 200122

Re: K191472
Trade/Device Name: Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: December 2, 2019
Received: December 2, 2019

Dear Raymond Luo:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191472

Device Name
Biospy Needle

Indications for Use *(Describe)*
The Biopsy Needle is intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone.

The 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 imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Date of preparation: 2020-1-28

1. Applicant:

Company Name: Ushare Medical Inc.
Company Address: 445 An Ji Zhong Road, San Zao Town, Zhuhai, Guangdong, P. R. China
Contact Person Name: Amy Wang (Ms.)
Title: Quality Manager
Tel: 0086-756-7516888
Mail: qm@usharemedical.com

Official Contact Person Information

Company Name: Shanghai Sungo Management Consulting Company Limited
Contact Person Name: Raymond Luo (Mr.)
Title: Technical Manager
Tel: 0086-21-68828050
Mail: fda.sungo@gmail.com

2. Current Device:

The proprietary name of the new device: Biopsy Needle
The generic name of the device: Instrument, Biopsy
Classification regulation: 21 CFR 876.1075
Classification: Class II.
Regulation Medical Specialty: Gastroenterology/Urology
Product code: KNW

3. Predicate device:

K number: K141552
Company: CareFusion
Address: 75 North Fairway Drive, Vernon Hills, IL 60061 USA
Predicate Device: Achieve Programmable Automatic Biopsy Systems

4. Intended use of the device:

The Biopsy Needle is intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone.

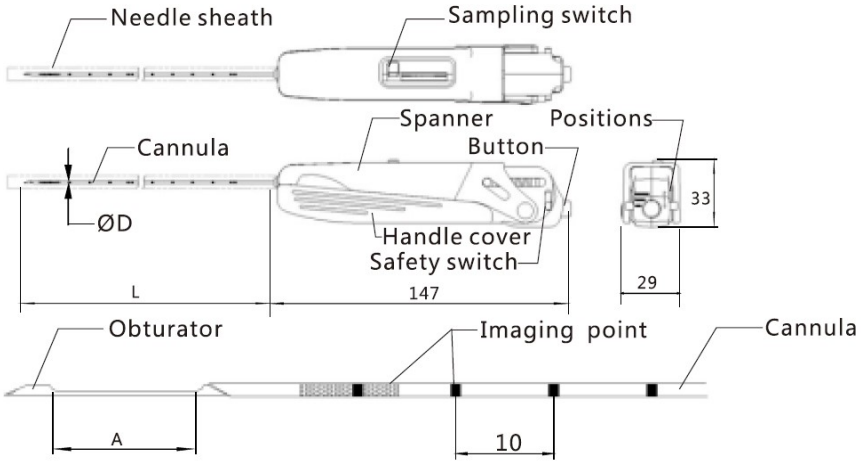
The Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic 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.

5. Device Description:

The sketch of the product structure and the dimension is shown in the figure below.



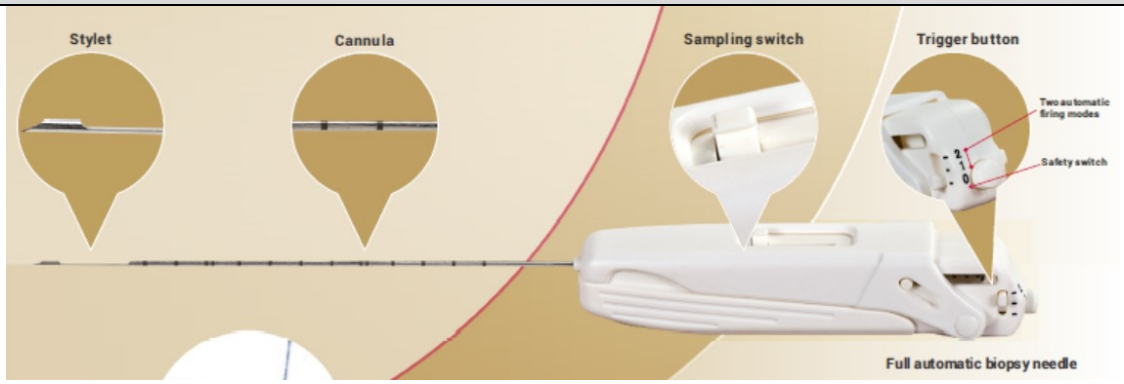
The Biopsy Needle are used to remove, by cutting, a specimen of tissue for microscopic evaluation. The organs in which the device may be used include but are not limited to breast, kidney, liver, prostate, spleen and lymph nodes plus various soft tissue masses. As the device is single use device, which is individually packaged sterile devices. In the package, there is a whole device with the structure shown in the picture above without any accessories. The packaging is compatible with the product's EO sterilization method. The sterilization validation confirms the packaging is qualified bacterial film to maintain the sterilization condition of the device.

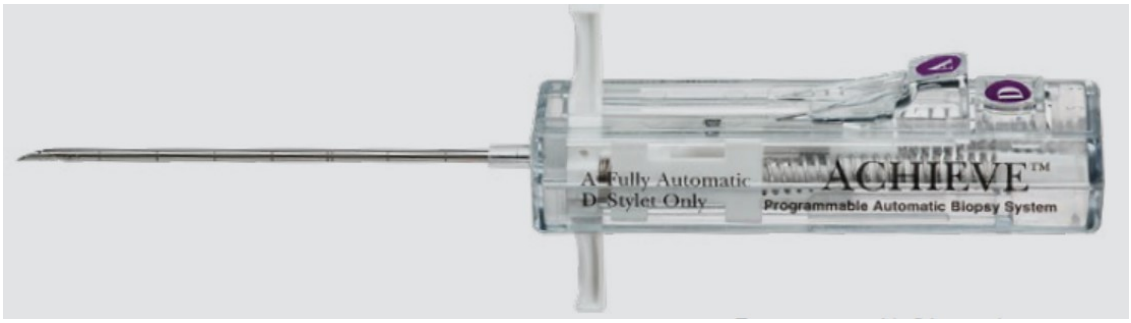
6. Current Device and Predicate Device Technical Characteristics

The proposed Biopsy Needle is substantially equivalent to the predicate Achieve Programmable Automatic Biopsy Systems with regards to claims, design, technology, and intended use. Refer to the Side by Side Comparison Table below.

6.1 Device Format

The subject disposable biopsy devices share the same format as the predicate devices for sterile, single use, and EO compatible packaging. Results from device testing indicate that subject devices are non-pyrogenic.

Device	Device Format
Current Device	

Predicate Device	

6.2 Technical Characteristics

Device	Current Device	Predicate Device
Manufacturer	Ushare Medical Inc. K191472	CareFusion K141552
Model Name	MBN Series Biopsy Needle	Achieve Programmable Automatic Biopsy Systems
Classification	Class II Device, KNW	Class II Device, KNW,
Intend use	The Biopsy Needle is intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone. The 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 imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic 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.	The Achieve Programmable Automatic Biopsy Systems is intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone. The Achieve Programmable Automatic Biopsy Systems 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 imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic 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.
Designated metric size	14G, 16G, 18G, 20G	12G, 14G, 16G, 18G, 20G
Length L(mm)	100mm, 150mm, 200mm	60mm, 90mm, 110mm, 150mm, 200mm, 250mm
Slot size	10mm, 15mm, 20mm	20mm
Cannula and Stylet	The cannula is designed with an outer cutting cannula having a sharpened tip and an inner	The cannula is designed with an outer cutting cannula having a sharpened tip and an inner

	stylet with sample slot.	stylet with sample slot.
Needle Advancement and Tissue Access	Biopsy Needle with guillotine coring and the predicate device with guillotine coring provide the clinician with the same single or two-stage (sequential) automatic advancement for fixed sample length for tissue penetration and cutting.	Same as current device
Mechanism of Action	single-hand automatic activation	Same as current device
Usability and Convenience	Provide design features that facilitate clinician use during biopsies: cannula centimeter marks, echogenic radiographic visibility, color coded needle hubs, and adjustable depth stops.	Same as current device
Standard	Biocompatibility: ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11) Sterilization: ISO11135, ISO11138, ASTM F1980, ISO11737-1, ISO10993-7, ISO11607 Performance: ISO9626	Biocompatibility: ISO10993-1 Sterilization: ISO11135, ISO11138, ASTM F1980, ISO11737-1, ISO10993-7, ISO11607 Performance: ISO9626
Comparison testing	Pressing parts, Pressing parts firing force, Cannula firing force, Safety switch, Sampling switch, Scale marks firmness, Total heavy metal content, Scale mark identification, Sampling structure, Sampling method, Penetration force, Biopsy Sample Testing, Ultrasound Visibility Testing	Pressing parts, Pressing parts firing force, Cannula firing force, Safety switch, Sampling switch, Scale marks firmness, Total heavy metal content, Scale mark identification, Sampling structure, Sampling method, Penetration force, Biopsy Sample Testing, Ultrasound Visibility Testing

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the same basic design as the predicate device. The comparison between the subject and predicate devices is based on the following:

- Same intended use
- Same indications for use
- Similar material types that meet ISO 10993 biocompatibility requirements
- Same sterilization methods
- Same fundamental technology/principal of operation/user interface

The disposable biopsy device needle designs display minor differences between the subject device and the predicate devices for gauge and needle length. The Max and Min size of the current device were covered by the predicate device. There is no significant risk raised by the difference.

7. Performance Testing

7.1 Biocompatibility and Sterility

Characteristic	Standard	Content
Biocompatibility	AAMI/ANSI/ISO 10993-1	Biological evaluation of Medical Devices Part 1: Evaluation and Testing
Biocompatibility	ISO 10993-4	Biological evaluation of medical devices--Part 4: Selection of tests for

		interactions with blood
Biocompatibility	ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
Biocompatibility	ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
Biocompatibility	ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
Sterilization	ISO11135	Medical Device, Validation and Routine Control of Ethylene Oxide Sterilization
Residuals	ISO10993-7	Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
Sterilization	ANSI/AAMI/ISO 11607	Packaging for Terminally Sterilized Medical Devices
Sterilization	ASTM F1980-07	Accelerated Aging of Sterile Barrier Systems

7.2 Device Shelf-life

The subject devices in their packaging were subjected to accelerated aging to simulate a 5 year shelf life (Treatment: 60°C, 162 days, <50% RH). The aged subject devices were tested for seal Strength, Dye Penetration, Vacuum Leak and Packaging resistance Bacterial performance.

7.3 Performance Testing

Characteristic	Standard	Content
Performance	ISO 9626:2016	Stainless Steel Needle Tubing for the Manufacture of Medical Devices.
Performance	The test was conducted to the predicate device and current device to compare their performance.	Pressing parts, Pressing parts firing force, Cannula firing force, Safety switch, Sampling switch, Scale marks firmness, Total heavy metal content, Scale mark identification, Sampling structure, Sampling method, Penetration force- Comparison of testing result of predicate and proposed devices to prove equivalency.
Performance		Biopsy Sample Testing – Comparison of samples obtained by predicate and proposed devices to prove equivalency.
Performance		Ultrasound Visibility Testing - Verification of the proposed device ultrasound visibility to ensure safety and effectiveness

8. Conclusion

The analysis of the Current Biopsy Devices by intended use, indications, anatomical locations, and mechanism of action supports that the subject devices are the same as those of the predicate devices.

Needle advancement for the subject device provides a single or two-stage (sequential) automatic advancement for fixed sample length for tissue penetration and cutting same as the predicate device. Materials of construction are those commonly used in medical devices and met biocompatibility requirements for medical devices. The sterile disposable devices also met the requirements for sterility per ISO and USP standards. There are no new questions concerning the safety and effectiveness of these devices.