



Food and Drug Administration
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August 2, 2016

Mermaid Medical A/S
% Ms. Rhonda Alexander
Registrar Corp.
144 Research Drive
Hampton, Virginia 23666

Re: K161409

Trade/Device Name: M-Biopsy Semi-Automatic Biopsy Instrument (N301)
M-Biopsy Coaxial Introducer Needle for Semi-automatic Biopsy
Instrument (N302)
M-Biopsy Semi-Automatic Instrument and Coaxial Introducer Needle
Set (NS301)

Regulation Number: 21 CFR 876.1075

Regulation Name: Gastroenterology-Urology Biopsy Instrument

Regulatory Class: Class II

Product Code: KNW

Dated: July 18, 2016

Received: July 20, 2016

Dear Ms. Alexander:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161409

Device Name

- (N301) M-Biopsy™ Semi-Automatic Biopsy Instrument
- (N302) M-Biopsy™ Coaxial Introducer Needle for Semi-Automatic Biopsy Instrument (N301)
- (NS301) M-Biopsy™ Semi Automatic Instrument and Coaxial Introducer Needle Set

Indications for Use (Describe)

(N301) Disposable Semi-Automatic Biopsy Instrument used for obtaining percutaneous or surgical histological biopsy samples from soft tissue by cutting from lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and pancreas, for microscopic examination.

(N302) Coaxial Introducer Needle is used as a guiding needle for (N301)

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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K161409

510 (k) Summary



Date prepared: July 21, 2016

I. Submitter

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II. Device

Trade name: M-Biopsy™ Semi-Automatic Biopsy Instrument (N301)
M-Biopsy™ Coaxial Introducer Needle for Semi-Automatic Biopsy Instrument (N302)
M-Biopsy™ Semi Automatic Instrument and Coaxial Introducer Needle Set (NS301)

Regulation Number: 876.1075
Classification Name: Gastroenterology-Urology Biopsy Instrument
Product Code: KNW
Classification Panel: Gastroenterology/Urology
Regulatory Class: Class II

Predicate Device: SuperCore™ Biopsy Instrument (K974814)

III. Device Description

The M-Biopsy™ Semi-Automatic Biopsy Instrument is a disposable lightweight spring loaded biopsy instrument with a biopsy needle fitted into a plastic handle.

The needle has a distal echogenic marker and centimeter markings to facilitate precise depth placement and may be visualized by X-ray, CT or ultrasound.

K161409

510 (k) Summary



The M-Biopsy™ Coaxial Introducer Needle has a trocar stylet and a distal echogenic marker and centimeter markings to facilitate precise depth placement and may be visualized by X-ray, CT or ultrasound.

The device (M-Biopsy™ Semi-Automatic Biopsy Instrument) is sold as a single device and as a set combination (M-Biopsy™ Semi-Automatic Biopsy Instrument and M-Biopsy™ Coaxial Introducer Needle).

The M-Biopsy™ Semi-Automatic Biopsy Instrument is used to obtain multiple core biopsy samples from soft tissue such as the liver, kidney, prostate, breast, lymph nodes, etc.

The M-Biopsy™ Coaxial Introducer Needle is used as a guiding needle for the M-Biopsy™ Semi-Automatic Biopsy Instrument.

The M-Biopsy™ device family can be used as transient use less than 60 minutes.

The M-Biopsy™ device family is available from Gauge 14 to Gauge 20 in different lengths ranging from 6 cm to 30 cm.

The M-Biopsy™ Semi-Automatic Biopsy Instrument consists of: Mandrill, Needle, House Lit, House base, Spring bushings, Spring, Cannula sledge, Trigger, Protecting sheath and Silicone coating.

The M-Biopsy™ Coaxial Introducer Needle consists of: Mandrill, Needle, Luer, Hub, Stopper, Protecting sheath and Silicone coating.

The M-Biopsy™ Semi Automatic Instrument and Coaxial Needle (set combination) consists of the above mentioned parts and a 3 Cavity clips to keep the part in place in the pouch.

IV. Indication for Use

(N301) Disposable Semi Automatic Biopsy Instrument is used for obtaining percutaneous or surgical histological biopsy samples from soft tissue by cutting from lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and pancreas for microscopic examination.

(N302) Coaxial Introducer Needle is used as a guiding needle for (N301).

V. Technological and Substantial Equivalence Summary

The M-Biopsy™ Semi-Automatic Biopsy Instrument is similar in fundamental design, function, device materials, sterilization, operating principle, intended use and technology as the predicate device “SuperCore™ Biopsy Instrument”.

K161409

510 (k) Summary



The modification from the predicate device includes:

- Shorter mandrill length than the predicate device
- Gauge size/length size print on the device. The predicate device does not have this.
- Loading and shooting force test 10 mm and 20 mm better or equal than the predicate device
- Lighter than the predicate device

The above mentioned differences do not raise new questions of safety and effectiveness.

VI. Performance Data

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. The device conformed to and/or passed the testing standard.

The M-Biopsy™ device family including packaging and sterilization met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or effective or performance issues were raised during the testing.

Design:	Geometric:
Handle design	Needle gauge
Loading handle and trigger	Needle size
Echogenic band on the distal end of the cannula	Stilet size
Cannula and Mandrill grind	Needle advancement / penetration depth
Mandrill protrudes from the cannula	Sample notch size
ID of the product Color code	Number of samples
Gauge size/length size print on the device	Spring operated
Visibility during incursion (Fluoroscopic, Ultrasound)	Single puncture and sample
Visualization of the insertion debt of the cannula. cm markers on the cannula shaft.	Safety features
Biopsy harvest method	Materials in contact with patient
Biopsy sample size	Target organs (anatomical)
Optional stroke length witch the operator chooses prior to use (10mm and 20mm)	Target population justification
Spring operated	Visualization techniques
	Method placement

K161409

510 (k) Summary



Mechanical test and Product comparisons test:	Performance tests:
Tensile pull testing	The performance test is a simulated biopsy test performed according to the IFU. The Biopsy needle is fired into two different medias as listed below. Each product has been fired 10 times each. Form and length of the biopsy sample was recorded.
Loading and shooting force test 10mm	
Loading and shooting force test 20mm	
Trigger firing force test	
Weight comparison test	
Packaging test:	Sterilization:
Sterile barrier Integrity	EO sterilization
Transportation test	Biocompatibility
World Wide Condition test	According to ISO 10993. See below.
Shelf life	

VII. Biocompatibility

The biocompatibility evaluation for the Semi-Automatic Biopsy Instrument and Coaxial Needle was conducted with the FDA and European standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk Management Process" as recognized by the FDA. The subject device conformed to or passed the following standards:

- MEM elution cytotoxicity test according to ISO 10993-5
- Sensitization test for delayed hypersensitivity or sensitization according to ISO 10993-10
- Irritation or Intracutaneous reactivity according to ISO 10993-10
- Acute Systemic Toxicity according to ISO 10993-11
- Haemocompatibility test according to ISO 10993-4

Conclusion

The subject devices, M-Biopsy™ Semi-Automatic Biopsy Instrument (N301), M-Biopsy™ Coaxial Introducer Needle for Semi-Automatic Biopsy Instrument (N302), and M-Biopsy™ Semi Automatic Instrument and Coaxial Introducer Needle Set (NS301), are similar to the predicate device in terms of materials, design, intended use, and performance. There are no differences, which negatively affect a finding of substantial equivalence. Thus, the subject device is considered to be substantially equivalent to the predicate.