July 12, 2019

Remington Medical, Inc.
Caitlin Senter
Regulatory Affairs Manager
6830 Meadowridge Court
Alpharetta, Georgia 30005

Re: K191315
Trade/Device Name: Remington Medical, Inc. Automatic Cutting Needle (NAC)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 14, 2019
Received: May 15, 2019

Dear Caitlin Senter:

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)*
K191315

Device Name
Remington Medical Inc. Automatic Cutting Needle (NAC)

Indications for Use *(Describe)*
Remington Medical, Inc. Automatic Cutting Needle (NAC) is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Remington MEDICAL

Traditional 510(k) Notification
Remington Medical Inc. Automatic Cutting Needle (NAC)

Section 5 – 510(k) Summary

Preparation Date	May 14, 2019
Applicant	Remington Medical, Inc. 6830 Meadowridge Court, Alpharetta, GA, USA 30005 Registration Number: 1056553 Owner/Operator Number: 9006473
Contact Person	Caitlin Senter, MS, RAC Regulatory Affairs Manager 470-719-1105 caitlins@remmed.com
Trade Proprietary Name(s)	Remington Medical, Inc. Automatic Cutting Needle (NAC)
Common Name (s)	Instrument, Biopsy
Classification Name	21 CFR 876.1075 Gastroenterology-urology biopsy instrument Product Code: KNW
Device Class:	II

Predicate Device:

Bard® Biopty-Cut® Biopsy Needle (K962077)

Description of the Device:

The Remington Medical Inc. Automatic Cutting Needle (NAC) is a device used for obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors in combination with compatible commercial biopsy instrument(s)/gun(s) which are FDA cleared and distributed in the US Market. The Automatic Cutting Needles (NAC) are available in five gauges (differentiated by color) and seven needle lengths. The Automatic Cutting Needle (NAC) is advanced via the compatible commercial biopsy instrument/gun into the desired tissue to obtain a sample for histological examination. The Automatic Cutting Needle (NAC) is a sterile, single patient use and non-pyrogenic device.

Intended Use/Indications for Use

Remington Medical, Inc. Automatic Cutting Needle (NAC) is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

Comparison to Predicate Device:

The technological characteristics (design, specifications, materials and performance) of the subject device and the predicate device are substantially equivalent.

Remington MEDICAL

Traditional 510(k) Notification
Remington Medical Inc. Automatic Cutting Needle (NAC)

	Subject Device: Remington Medical, Inc. Automatic Cutting Needle (NAC)			**Predicate Device: Bard® Biopty-Cut® Biopsy Needle (K962077).**		
Device Class FDA Product Code Regulation	Class II KNW 21 CFR 876.1075 (Instrument, Biopsy)			Class II KNW 21 CFR 876.1075 (Instrument, Biopsy)		
Indications for Use Statement	Remington Medical, Inc. Automatic Cutting Needle (NAC) is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.			The device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.		
Type of Use	Prescription Use			Prescription Use		
Cannula Material	Metal, Stainless Steel			Metal, Stainless Steel		
Cannula Depth Marking	Wide Band, Centimeter Gradations			Wide Band, Centimeter Gradations (Optional)		
Etched Tip	Standard			Optional		
Cannula Hub Material	Color-coded Plastic (Polycarbonate) or Color-coded Plastic (Acrylonitrile butadiene styrene (ABS))			Color-coded Plastic (Polycarbonate)		
Stylet Material	Metal, Stainless Steel			Metal, Stainless Steel		
Stylet Hub Material	Color-coded Plastic (Polycarbonate) or Color-coded Plastic (Acrylonitrile butadiene styrene (ABS))			Color-coded Plastic (Polycarbonate)		
Gauge/Length (centimeters)/Color Depiction	12 GA	10, 13, 16, 20	Pale Blue*	12 GA	10, 16, 20	Blue*
	14 GA	10, 12, 13, 16, 20	Pale Green*	14 GA	10, 16, 20	Green
	16 GA	10, 13, 16, 20, 25	White*	16 GA	10, 16, 20, 25, 30	Purple
	18 GA	10, 13, 16, 20, 25, 30	Pink*	18 GA	10, 16, 20, 25, 30	Pink
	20 GA	10, 13, 16, 20	Yellow*	20 GA	10, 16, 20	Yellow
	*Per ISO 6009:2016(E)			*Assumption per ISO 6009:2016(E)		
Mechanism of Action	Single puncture and sample			Single puncture and sample		
Principle of Operation	Cutting			Cutting		
Final Needle Assembly Protection	Sheath			Sheath		
Sterilization Method	ETO			ETO		

Performance Data:

To demonstrate that the subject device Remington Medical Inc. Automatic Cutting Needle (NAC) is as safe and as effective as the predicate device Bard® Biopty-Cut® Biopsy Needle, materials, technological characteristics and performance criteria were evaluated. The following tests were performed on the subject device

- Dimensional Requirements

- Stylet / Cannula to Hub Tensile Strength
- Equipment Interface
- Integrity of the Sterile Barrier
- Biocompatibility
- Pyrogenicity
- Sterility Assurance
- Distribution Simulation

In addition, the following ex vivo tests were performed on the subject device and predicate device:

- Simulated Use – Soft Tissue Sampling

Clinical testing:

No clinical testing was required.

Conclusion:

The results of the non-clinical testing demonstrated that the subject device, Remington Medical Inc. Automatic Cutting Needle (NAC), is substantially equivalent to the predicate device, Bard® Biopty-Cut® Biopsy Needle, with respect to intended use, materials, design, and technological characteristics.