April 2, 2020

MEDAX S.R.L. UNIPERSONALE
Stefano Cavalieri
Quality Assurance Manager
Via R. Piva 1/A
Poggio Rusco Mantova, Italy 46025

Re: K192101
Trade/Device Name: Medax Soft Tissue Biopsy System: MEDONE ULTRA and MEDEXTRA
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 21, 2020
Received: February 25, 2020

Dear Stefano Cavalieri:

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)*
K192101

Device Name
Medax Soft Tissue Biopsy System

Indications for Use *(Describe)*

MEDONE ULTRA Soft tissue programmable automatic biopsy system: biopsy system has been designed to be used for histological biopsy of soft tissues (such as breast, kidney, liver, prostate and various soft tissue masses). It is not intended for use in bone biopsy.

MEDEXTRA lymph node biopsy system with rectangular shaped cannula and adjustable penetration depth: is intended for use in obtaining biopsies from lymph nodes and other superficial non-vascular lumps. It is not intended for use in bone, deep visceral structures and breast biopsy.

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, AS REQUIRED BY 21 CFR 807.92

Submitter's Name **Address** **Establishment Registration Number**	MEDAX S.R.L. UNIPERSONALE Via R. Piva 1/A Poggio Rusco Mantova, ITALY 46025 3007648417
Summary Preparation Date	March 30th 2020
Contact Person **Telephone Number** **Fax Number**	Stefano Cavalieri Quality Assurance Manager +39.0535.1813915 +39.0535.1812744

Medax Soft Tissue Biopsy System

Name of the Device	Medax Soft Tissue Biopsy System
Common name of the device	Medax Soft Tissue Biopsy System (MEDONE ULTRA, MEDEXTRA)
Classification Name and class	Instrument, Biopsy Device Class: II Product Code: KNW Regulation Number 21 CFR 876.1075
Performance Standard	− ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods − ASTM F899-12b Standard Specification for Wrought Stainless Steels for Surgical Instruments − ISO 10993:2009 series and FDA Guidance on Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ", Date:06/16/16 − ISO 11607-1.2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems − ISO 11737:2006 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
DESCRIPTION of the device:	Medax Soft Tissue Biopsy System portfolio is composed by single use devices intended to obtain biopsy samples from soft tissue for histological examinations. MEDONE ULTRA Devices are available in different gauge dimensions (identified by different colors) and needle length.
Indications for Use	MEDONE ULTRA Soft tissue programmable automatic biopsy system: biopsy system has been designed to be used for histological biopsy of soft tissues (such as breast, kidney, liver, prostate and various soft tissue masses). It is not intended for use in bone biopsy.

	MEDEXTRA lymph node biopsy system with rectangular shaped cannula and adjustable penetration depth: is intended for use in obtaining biopsies from lymph nodes and other superficial non-vascular lumps. It is not intended for use in bone or deep visceral structures.
Comparison of Technological Characteristics	In vitro bench testing was performed to support a determination of substantial equivalence (refer to performance testing below) between Medax Soft Tissue Biopsy System portfolio and predicate devices. The results of these tests provide reasonable assurance that proposed devices have been designed and tested to assure conformance to the requirements for its intended use and perform comparably to the existing predicate devices.
Performance Testing (non-clinical)	In vitro bench tests were carried out, according to the requirements of FDAs document Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s and applicable standards. The following areas have been tested and/or evaluated: - Performance and functional tests according to ISO 9626; - Biocompatibility tests according to ISO 10993 series and FDA Guidance on Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process " - Bioburden and Sterility tests; - Validation of the EtO Sterilization process, - Packaging validation, - Labelling evaluation, - EtO Residual, Ethylene Chlorohydrin and Ethylene Glycol according to EN ISO 10993-7. Results from these performances evaluation demonstrated that the Medax Soft Tissue Biopsy System devices met the acceptance criteria defined in the product specification and performed comparably to the predicate device.
SUBSTANTIAL EQUIVALENCE:	Medax Soft Tissue Biopsy System devices are identical to the predicate device in terms of intended use, indications for use and medical technique. Equivalence has been identified as follows:

Medax Soft Tissue Biopsy System Device	**Predicate Device**		
	Name	**Manufacturer**	**510(k) ID**
MEDONE ULTRA Soft tissue programmable automatic disposable biopsy system	Achieve® Programmable Automatic Biopsy Systems	MERIT MEDICAL	K141552, cleared by FDA on June 10, 2014
MEDEXTRA lymph node biopsy system with rectangular shaped cannula	Velox 2	Medax s.r.l.	K181803, cleared by FDA on October 18, 2018

A comparison of the Medax Soft Tissue Biopsy System with the predicate devices is provided in **Table 1**. This table details the closely shared indications for use, materials and design and principle of operation between the devices, therefore establishing substantial equivalence of the devices subjected of this current submission with the predicate devices.

Table 1 - Comparison of the Medax Soft tissue Biopsy System to the predicate Soft tissue Biopsy System devices.

	Subject Device **Medax MEDONE ULTRA** Programmable Automatic disposable Biopsy System	**Predicate device** Achieve® Programmable Automatic Biopsy Systems (K141552)
Regulation Number	21 CFR §876.1075	Same as current device
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.
Indication for Use	MEDONE ULTRA 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	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
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same as current device
Mechanics of Operation	Single hand automatic activation	Same as current device
Model Available (Needle, Cannula(S), And Stylet Size: Diameter, Gauge and Length)	Needle cannula from 14G to 20G Length from 60 mm to 200 mm	Needle cannula from 12G to 20G Length from 60 mm to 200 mm
Patient/Tissue Contact Materials	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 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.
Biocompatibility Requirements	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts
Description of The Sterilization Method	Sterilized by Ethylene Oxide (EO	Sterilized by Ethylene Oxide (EO)

The lengths of the predicate are exactly equivalent to the lengths range of the proposed device. The predicate device has a larger number of versions in term of diameters. The diameters of the proposed devices fall within the range of the predicate devices and therefore the substantially equivalence is demonstrated.

	Subject Device MEDEXTRA	**Predicate device VELOX 2 (**K181803)
Regulation Number	21 CFR §876.1075	Same
Device Description	Disposable semi-automatic spring-loaded guillotine style biopsy system with adjustable penetration depth and rectangular shaped cannula for histological biopsy on lymph nodes and other superficial non-vascular lumps.	Disposable semi-automatic spring-loaded guillotine style biopsy system with adjustable penetration depth for histological biopsy on soft tissue.
Indication for Use	MEDEXTRA is intended for use in obtaining biopsies from soft tissues such as lymph nodes and other superficial non-vascular lumps. It is not intended for use in bone, deep visceral structures and breast biopsy.	The device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue masses. It is not intended for use in bone biopsy.
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities
Needle Advancement/ Penetration Depth	From 12 or 22 mm	From 15 mm or 22 mm
Sample Notch Size	Max 20 mm	Max 20 mm
Mechanics of Operation	Single hand automatic activation	Single hand automatic activation
Model Available (Needle, Cannula(S), And Stylet Size: Diameter, Gauge and Length)	Needle cannula 4,6mm x 2.10mm Single length 100mm	Needle cannula from 14G (2.1mm) to 20G (0.8mm) Length from 80 mm to 300 mm
Patient/Tissue Contact Materials	Cannula and mandrel are made of stainless steel AISI 304. Only Stainless steel AISI 304 is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made of stainless steel AISI 304. Only Stainless steel AISI 304 is in direct surgical contact with all soft tissues of the patient.
Biocompatibility Requirements	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts
Description of The Sterilization Method	Sterilized by Ethylene Oxide (EO) In accordance with ISO 11135-1	Sterilized by Ethylene Oxide (EO) In accordance with ISO 11135-1

The rectangular shape of the subject device Medextra cannula has equivalent functionality if compared with the rounded shape of the predicate cannula.
This difference does not affect the safety and effectiveness of the proposed device.
The predicate device has a larger number of versions in term of length. The length of the proposed devices falls within the range of the predicate devices and therefore the substantially equivalent is demonstrated.

CONCLUSION
Based on the safety and performance testing, technological characteristics and the indications for use, the devices proposed Medax Soft Tissue Biopsy System, have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to the identified predicate device.