DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 13, 2017

MEDAX S.R.L. Unipersonale
% Mr. Mario Gennari
Regulatory Consultant
Gemar S.R.L.
Via G. Puccini 1
Medolla, I-41036 Italy

Re: K172344
Trade/Device Name: Medax Biopsy Systems II
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: August 28, 2017
Received: August 31, 2017

Dear Mr. Gennari:

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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

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)*
K172344

Device Name

Medax Biopsy Systems II

Indications for Use *(Describe)*

MEDONE Soft tissue automatic disposable biopsy system: MEDONE biopsy system 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.

MEDCUT automatic disposable biopsy system : MEDCUT biopsy system 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.

MEDEM Mallarmé bone marrow aspiration needle: MEDEM biopsy needle must be used for bone marrow aspiration from sternum or iliac crest.

MEDBONE Bone marrow biopsy system: MEDBONE biopsy needle must be used for bone marrow aspiration and the posterior iliac crest biopsy.

MEDLOCK Bone marrow biopsy and aspiration system: MEDLOCK biopsy system must be used for bone marrow aspiration and the posterior iliac crest 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

I. SUBMITTER

MEDAX S.R.L. UNIPERSONALE
Via R. Piva 1/A
Poggio Rusco, 46025
Mantova, ITALY
Phone: +39.0535.1813915
Fax: +39.0535.1812744

Contact Person: Mario Gennari, Regulatory Consultant
Telephone Number +39.0535.731216
Fax Number +39.0535. 731216

Date Prepared: October 27th, 2017

II. DEVICE

Name of the Device: Medax Biopsy Systems II
Common name of the device: Medax Biopsy Systems II (MEDONE, MEDCUT, MEDEM, MEDBONE, MEDLOCK)
Classification Name: Instrument, Biopsy
Regulatory Class: Device Class: II
Product Code: KNW

III. PREDICATE DEVICE

Substantial equivalence has been identified as follows:

Medax Biopsy Systems II Device	**Predicate Device**		
	Name	**Manufacturer**	**510(k) ID**
MEDONE Automatic disposable Biopsy System	Avangarde Biopsy System	MEDAX S.R.L. UNIPERSONALE	K142125 - New Medax biopsy system
MEDCUT Automatic disposable Biopsy System	Monopty Disposable Core Biopsy Instrument	Bard Peripheral Vascular, Inc	K133948 - Bard-Monopty disposable core biopsy instrument
MEDEM Mallarme bone marrow aspiration system	PERFECTUS Bone marrow biopsy device	MEDAX S.R.L. UNIPERSONALE	K092338 - Medax biopsy system
MEDBONE bone marrow biopsy system	NEO OXUS Bone marrow biopsy system	MEDAX S.R.L. UNIPERSONALE	K092338 - Medax biopsy system
MEDLOCK Bone marrow biopsy and aspiration system	TOTALLY REMOVE: Needle for bone-marrow biopsy	BIOPSYBELL S.R.L.	K130616-MANUAL-BONE-MARROW-BIOPSY-NEEDLES, SEMI-

Medax Biopsy Systems II Device	Predicate Device		
	Name	**Manufacturer**	**510(k) ID**
			AUTOMATIC-BIOPSY-NEEDLES, AUTOMATIC-BIOPSY-NEEDLES

Medax Biopsy Systems II devices are identical to the predicate device in terms of intended use, indications for use and medical technique.
Based on the safety and performance testing, technological characteristics and the indications for use, the devices proposed Medax Biopsy Systems II, have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to the identified predicate device.

IV. DEVICE DESCRIPTION

Medax Biopsy Systems II portfolio is composed by single use devices intended to obtain biopsy samples from soft tissue or bone (depending on product family) for histological examinations.
Devices are available in different gauge dimensions (identified by different colors) and needle length.

V. INDICATIONS FOR USE

MEDONE Soft tissue automatic disposable biopsy system: MEDONE biopsy system is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue masses.
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MEDCUT automatic disposable biopsy system: MEDCUT biopsy system is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue masses.
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MEDLOCK Bone marrow biopsy and aspiration system: MEDLOCK biopsy system must be used for bone marrow aspiration and the posterior iliac crest biopsy.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In vitro bench testing were performed to support a determination of substantial equivalence (refer to performance testing below) between Medax Biopsy Systems II 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.

VII. PERFORMANCE DATA

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,
- EtO Residual, Ethylene Chlorohydrin and Ethylene Glycol according to EN ISO 10993-7.
- Packaging validation,
- Labelling evaluation.

Applicable standards for Medax Biopsy Systems II portfolio are the following:

- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods;
- ISO 10993-1:2009 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;
- ASTM F899-12b Standard Specification for Wrought Stainless Steels for Surgical Instruments.

Results from these performances evaluation demonstrated that the Medax Biopsy Systems II devices met the acceptance criteria defined in the product specification and performed comparably to the predicate device.

VIII. CONCLUSIONS

Based on the safety and performance testing, technological characteristics and the indications for use, the devices proposed Medax Biopsy Systems II, have been demonstrated to be appropriate for their intended use and are considered substantially equivalent to the identified predicate devices (currently marketed for the same indication purpose).