April 2, 2020

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

Re: K192099
Trade/Device Name: Medax Bone Marrow Biopsy and Aspiration System: MED-B, MED-I , MED-J, MED-L, and MED-S
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)*
K192099

Device Name
Medax Bone Marrow Biopsy and Aspiration System

Indications for Use *(Describe)*

MED-I Bone Marrow Aspiration Needle: MED-I biopsy system has been designed to be used in bone marrow aspiration procedures from iliac crest or sternum.

MED-S Bone Marrow Aspiration Needle: MED-S biopsy system has been designed to be used in bone marrow aspiration procedures from sternum or iliac crest.

MED-L Bone Marrow Biopsy and Aspiration System: MED-L biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy.

MED-B Bone Marrow Biopsy System: MED-B biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy.

MED-J Bone Marrow Biopsy and Aspiration System: MED-J biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy. Note: Do not use in sternal procedure.

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 Bone Marrow Biopsy and Aspiration System

Name of the Device	Medax Bone Marrow Biopsy and Aspiration System
Common name of the device	Medax Bone Marrow Biopsy and Aspiration System (MED-B, MED-I, MED-J, MED-L, MED-S).
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 11737-1:2006 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
DESCRIPTION of the device:	Medax Bone Marrow Biopsy and Aspiration System portfolio is composed by single use devices intended to obtain biopsy samples from bone for histological examinations. Devices are available in different gauge dimensions (identified by different colors) and needle length.
Indications for Use	MED-I Bone Marrow Aspiration Needle: MED-I biopsy system has been designed to be used in bone marrow aspiration procedures from iliac crest or sternum. MED-S Bone Marrow Aspiration Needle: MED-S biopsy system has been designed to be used in bone marrow aspiration procedures from sternum or iliac crest.

	MED-L Bone Marrow Biopsy and Aspiration System: MED-L biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy. MED-B Bone Marrow Biopsy and aspiration System: MED-B biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy. MED-J Bone Marrow Biopsy and Aspiration System: MED-J biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy. Note: Do not use in sternal procedure.
Comparison of Technological Characteristics	Documental comparisons were performed to support a determination of substantial equivalence (refer to performance testing below) between Medax Bone Marrow Biopsy and Aspiration System portfolio and predicate devices. The results of these evaluation 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 Bone Marrow Biopsy and Aspiration System devices met the acceptance criteria defined in the product specification and performed comparably to the predicate device.

SUBSTANTIAL EQUIVALENCE:

Medax Bone Marrow Biopsy and Aspiration 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 Bone Marrow Biopsy and Aspiration Systems Device	**Predicate Device**		
	Name	**Manufacturer**	**510(k) ID**
MED-I Bone marrow aspiration needle	**HANDLEX** Bone marrow aspiration needle	MEDAX S.R.L. UNIPERSONALE	K181803 - Medax Biopsy System III, cleared by FDA on 10/18/2018
MED-S Bone marrow aspiration needle	**PERFECTUS** Bone marrow aspiration needle	MEDAX S.R.L. UNIPERSONALE	K181803 - Medax Biopsy System III, cleared by FDA on 10/18/2018
MED-L Bone marrow biopsy and aspiration system	**MEDLOCK** Bone marrow biopsy and aspiration system	MEDAX S.R.L. UNIPERSONALE	K172344 - Medax Biopsy System II, cleared by FDA on 11/13/2017
MED-B Bone marrow biopsy and aspiration system	**MEDBONE** Bone marrow biopsy system	MEDAX S.R.L. UNIPERSONALE	K172344 - Medax Biopsy System II, cleared by FDA on 11/13/2017
MED-J Bone Marrow Biopsy and Aspiration System	**BD/Carefusion, Original Jamshidi™ bone marrow biopsy aspiration needles**	Carefusion	K171531 - Jamshidi Bone Marrow Biopsy/Aspiration Needle, cleared by FDA on 9/11/2017

A comparison of the Medax Bone Marrow Biopsy and Aspiration 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 Bone Marrow Biopsy and Aspiration System to the predicate Bone Marrow Biopsy and Aspiration devices.

	Subject Device: **Medax MED-I** **Bone Marrow Aspiration Needle**	**Predicate Device:** **HANDLEX Bone Marrow Aspiration Needle (K181803)**
Regulation Number	21 CFR §876.1075	Same
Device Description	Disposable bone marrow aspiration needle, used to aspirate bone marrow from sternum or iliac crest. The device is comprised of an outer cannula with handle and inner stylet.	Disposable bone marrow aspiration needle, used to aspirate bone marrow from sternum or iliac crest. The device is comprised of an outer cannula with handle and inner stylet.
Indication for Use	The device is intended for aspiration of bone marrow from sternum or iliac crest.	The device is intended for aspiration of bone marrow from sternum or iliac crest.
Target Population	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases
Mechanics of Operation	Manual instrument	Manual instrument
Model Available (Needle, cannula(S), And Stylet Size: Diameter, Gauge And Length)	Needle cannula from 14G to 18G	Needle cannula from 14G to 18G
	Available with aspiration tip and explant/transplant tip - Length from 30 mm to 110 mm	Available with aspiration tip and explant/transplant tip - Length from 30 mm to 110 mm
Patient/Tissue Contact Materials	Stainless steel AISI 304 is in direct surgical contact with all soft tissues of the patient.	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
Sterilization	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1
	Subject Device **Medax MED-S** **Bone Marrow Aspiration Needle**	**Predicate Device** **PERFECTUS Bone Marrow Aspiration Needle (K181803)**
Regulation Number	21 CFR §876.1075	Same
Device Description	Disposable bone marrow aspiration needle with adjustable depth setter, used to aspirate bone marrow from sternum or iliac crest.	Disposable bone marrow aspiration needle with adjustable depth setter, used to aspirate bone marrow from sternum or iliac crest.
Indication for Use	The device is intended for aspiration of bone marrow from sternum or iliac crest.	The device is intended for aspiration of bone marrow from sternum or iliac crest.
Target Population	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases
Mechanics of Operation	Manual instrument	Manual instrument
Model Available (Needle, cannula(S), And Stylet Size: Diameter, Gauge And Length)	Needle cannula from 14G to 18G	Needle cannula from 14G to 18G
	Available with aspiration tip and explant/transplant tip - Length from 20 mm to 150 mm	Available with aspiration tip and explant/transplant tip - Length from 20 mm to 150 mm
Patient/Tissue Contact Materials	Stainless steel AISI 304 is in direct surgical contact with all soft tissues of the patient.	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
Sterilization	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1

	Subject Device **Medax MED-L** **Bone Marrow Aspiration System**	**Predicate Device** **MEDLOCK Bone Marrow Biopsy And Aspiration System K172344**
Regulation Number	21 CFR §876.1075	Same
Device Description	Disposable device, was designed for bone-marrow biopsy from the iliac crest. The device consists of an outer cannula with handle and an inner stylet. The needle is equipped with a universal Luer-Lock connector for eventual cytological aspiration.	Disposable MEDLOCK device was designed for bone-marrow biopsy from the iliac crest. The device consists of an outer cannula with handle and an inner stylet. The needle is equipped with a universal Luer-Lock connector for eventual cytological aspiration.
Indication for Use Including Specific Target Organs	biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy.	biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy.
Target Population	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases
Mechanics of Operation	Manual instrument	Manual instrument
Model Available (Needle, Cannula(S), And Stylet Size: Diameter, Gauge And Length)	Needle cannula from 7G to 13G	Needle cannula from 8G to 13G
	"MED-L ": Needle length from 100 mm to 150 mm	"MEDLOCK ": Needle length from 70 mm to 150 mm
Patient/Tissue Contact Materials	Stainless steel AISI 304 is in direct surgical contact with all soft tissues of the patient.	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
Sterilization	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1
	Subject Device **Medax MED-B** **Bone Marrow Aspiration System**	**Predicate Device** **MEDBONE Bone Marrow Biopsy System (K172344)**
Regulation Number	21 CFR §876.1075	Same
Device Description	Disposable bone marrow biopsy needle Is comprised of an outer cannula with an inner stylet. The needle has an ergonomic handle at whose base a Luer lock cone is fitted.	Disposable bone marrow biopsy needle Is comprised of an outer cannula with an inner stylet. The needle has an ergonomic handle at whose base a Luer lock cone is fitted.
Indication for Use	The device is intended to retrieve bone marrow and bone samples from the iliac crest.	The device is intended to retrieve bone marrow and bone samples from the iliac crest.
Target Population	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases
Mechanics of Operation	Manual instrument	Manual instrument
Model Available (Needle, Cannula(S), And Stylet Size: Diameter, Gauge And Length)	Needle cannula from 7G to 13G	Needle cannula from 8G to 13G
	Available with Explant Transplant version - length from 70 mm to 150 mm	Available with Explant Transplant version "MED-B ": Needle length from 100 mm to 150 mm
Patient/Tissue Contact Materials	Stainless steel AISI 304 is in direct surgical contact with all soft tissues of the patient.	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

	Subject Device **Medax MED-B** **Bone Marrow Aspiration System**	**Predicate Device** **MEDBONE Bone Marrow Biopsy System (K172344)**
Sterilization	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1
	Subject Device **Medax MED-J** **Bone Marrow Aspiration System**	**BD/Carefusion, Original Jamshidi™** **Bone Marrow Biopsy Aspiration Needles (K171531)**
Device Description	Disposable bone marrow manual biopsy needle is used to retrieve bone marrow aspirate and core biopsy samples from bone and/or bone marrow. The devices are comprised of an outer cannula with a handle and an inner stylet. The specimen is contained within the cradle during withdrawal from the cannula.	The Jamshidi devices are manual, sterile, disposable needles intended to obtain bone marrow aspirate and core biopsy samples from bone and/or bone marrow. The devices are comprised of an outer cannula with a handle and an inner stylet. The specimen is contained within the cradle during withdrawal from the cannula.
Indication for Use	Med-J biopsy system has been designed to be used in bone marrow aspiration and the posterior iliac crest biopsy.	The device is intended to use in aspirating bone marrow and obtaining biopsy from posterior iliac crest
Target Population	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases	Individuals requiring biopsy for bone marrow sampling for abnormality in blood cells and signs of diseases
Mechanics of Operation	Manual instrument	Manual instrument
Model Available (Needle, cannula(S), And Stylet Size: Diameter, Gauge And Length)	Needle cannula from 8G to 13G	Needle cannula from 8G to 13G
	MED-J bone marrow biopsy/aspiration system ": Needle length from 50 mm to 150 mm	"Jamshidi bone marrow biopsy/aspiration needle ": Needle length from 50 mm to 152 mm
Patient/Tissue Contact Materials	Stainless steel AISI 304 is in direct surgical contact with all soft tissues of the patient.	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
Sterilization	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1	Supplied sterile via Ethylene Oxide (EO), according to ISO 11135-1

Conclusion

Conclusion

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