DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 19, 2017

Möller Medical GmbH
Ms. Angela Kikowatz
Regulatory Affairs Manager
Wasserkuppenstrasse 29-31
Fulda, 36043 Germany

Re: K162588
Trade/Device Name: Möller Medical Biopsy Needles and Systems
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 31, 2017
Received: June 5, 2017

Dear Ms. Kikowatz:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162588

Device Name
Möller Medical Biopsy Needles and Systems

Indications for Use *(Describe)*

The Möller Medical Biopsy Needles and Systems are used to obtain core samples and aspiration from tissue by biopsy. The various wall thicknesses, diameters, tip geometries and cutting techniques of the different hollow needle types and biopsy systems affect the quality of the biopsy specimen.

Model BOW-1060 bone marrow biopsy systems are intended for the atraumatic taking of specimens from and inside bones. Application areas of the products are bone respectively bone marrow.

Model BOW-1070 bone marrow aspiration biopsy set is intended for aspiration in the area of the sternum or iliac crest. Application areas of the products are bone respectively bone marrow.

Model BOY-1080 bone biopsy needle set has been designed for atraumatic bone biopsy. Application areas of the products are bone respectively bone marrow.

Model DNG-10XX single-use biopsy needles are exclusively intended for hollow needle biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions and are combined with biopsy guns.

Model full-sCore® DNG-2020 disposable biopsy needles are intended only for biopsies on soft tissue and tissue from soft, internal organs such as liver, kidney, breast, lung and various soft tissue lesions , and should be used with the Möller Medical Blue (RBG-1000-10-1000) biopsy gun.

Model FNB and MBY single-use biopsy needles are exclusively intended for hollow needle biopsies of soft tissue for example from pleura cavity and associated organs, abdominal cavity and associated organs like breast, liver, prostate and kidney.

Model COX is for safe needle guidance and for taking several biopsy specimens, for example from liver, kidney, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions, with only one single puncture.

Model ABG disposable automatic biopsy guns are intended for biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions.

Model SBG disposable semiautomatic biopsy guns are intended for biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions.

Model Möller Medical Blue RBG is a reusable, automatic biopsy gun that is intended exclusively for use with DNG-1020 / full-sCore® DNG-2020 disposable needles for core needle biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions.

When used for breast biopsy, the product is for diagnosis only. The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality; e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal of

using standard surgical procedures.

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

1. Submitter

Submitter:	Möller Medical GmbH Wasserkuppenstrasse 29-31 36043 Fulda, Germany Tel.: +49 (0) 661-94195-0 Fax: +49 (0) 661-94195-850 Establishment Registration Number: 3006611221
Contact Person:	Grant Geckeler Free lance consultant 1612 Jenks Drive Corona, CA 92880 Phone: +1 858 603 1838 E-mail: grant.geckeler@gmail.com
Date Prepared:	September 01, 2016

2. Device

Trade name:	Möller Medical Biopsy Needles and Systems Consists of: Bone and Bone Marrow Aspiration Needles, Fine Needles, Disposable Needles for Biopsy Guns, Coaxial Needles, Manual Cut Biopsy Needles, Semi-automatic and automatic Biopsy Guns
Common or Usual Name:	Biopsy Instruments
Classification Name:	Instrument Biopsy (21 CFR 876.1075)
Regulatory Class:	II
Product Code:	KNW

3. Predicate Device

The Möller Medical Biopsy Portfolio is coincident with other different biopsy products which are already FDA approved and distributed in the US market. Table 1 shows the identified appropriate predicate devices for the Möller Medical Biopsy Portfolio with the corresponding 510(k) number. The product codes and classes are also named.

Table 1: Predicate devices

Möller Medical Product	Predicate Device with 510(k) No.	Code and Class
Möller Medical Blue Biopsy Gun (RBG-xxxx)	Pro-Mag Ultra 2.2 Automatic Biopsy Instrument; Pro Mag Ultra Biopsy Needles, Pro-Mag Ultra Automatic Biopsy Instrument 510(k) No.: K980226	KNW Class II
Bone Marrow Biopsy System (BOW-1060)	Bone Marrow Aspiration Needles; Bone Marrow Biopsy Trays; Bone Marrow Harvest Needles; Osty-Core Bone Biopsy Needles ; Pediatric Bone Marrow Access Needles; T-Lok Bone Marrow Bone Marrow Aspiration Needles; Bone Marrow Biopsy Trays; Bone Marrow Harvest Needles; Osty-Core Bone Biopsy Needles ; Pediatric Bone Marrow Access Needles; T-Lok Bone Marrow Needles 510(k) No.: K980196	KNW Class II
Bone Marrow Aspiration Biopsy (BOW-1070)		
Bone Biopsy Needles (BOY-1080)		
Fine Needle Biopsy (FNB-xxxx)	Fine Needle Aspiration (FNA) Biopsy Needles Chiba; Franseen; Green; MaxiCELL; Pro-Cut; Spinal; Trocar; Turner; Westcott Soft Tissue Biopsy Needles 510(k) No.: K980122	KNW Class II
Disposable Needles for Biopsy Gun (DNG)		
DNG-1010	ACN, SACN, Biopsy Needle; 510(k) No.: K974446	KNW Class II
DNG-1020; DNG-1030	Pro-Mag Ultra 2.2 Automatic Biopsy Instrument; Pro-Mag Ultra Biopsy Needles; Pro-Mag Ultra Automatic Biopsy Instrument 510(k) No.: K980226	KNW Class II
DNG-1040	Magnum Core Tissue Biopsy Needle Model MN1820, RP Cutting Needle Model RP-1820, MCN Core Tissue Biopsy Needle Model MCN 510(k) No.: K111529	KNW Class II

Möller Medical Product	Predicate Device with 510(k) No.	Code and Class
fullsCore® Biopsy Needle (DNG-2020)	BioPince FullCore Biopsy Instrument 510(k) No.: K904987	KNW Class II
Semi-automatic Biopsy Gun (SBG-xxxx)	Speedybell 510(k) No.: K010735	KNW Class II
Automatic Biopsy Gun (ABG-xxxx)	Manual-Bone-Marrow-Biopsy-Needles, Semi-Automatic-Biopsy-Needles, Automatic-Biopsy Needles 510(k) No.: K130616	KNW Class II
Coaxial Needles (COX-xxxx)	Co-Axial Introducer Needle 510(k) No.: K980004	KNW Class II
Manual Cut Biopsy (MBY-xxxx)	18 Gauge Tru-Cut Biopsy Needle 510(k) No.: K960509	KNW Class II

The presented Möller Medical products have the same indication and the same technology as the selected predicate devices.

4. Device Description

Möller Medical Blue RBG

The Möller Medical Blue RBG is a re-usable biopsy gun to be used with corresponding needles to obtain core samples from soft tissue. It is a re-usable device, which has to be reprocessed. The biopsy needles used with this device are disposable products.

The Möller Medical Blue RBG is intended to be used with the DNG-1020 and the DNG-2020 needles.

The following steps are needed to prepare for the puncture. The first step is to open the cover of the Möller Medical Blue.

Generally spoken the insertion of biopsy needles into the re-usable biopsy gun is dependent from the biopsy needle. It is important that the plastic hubs of the compatible needles are positioned carefully onto the locking pins.

After needle insertion into the device the cover of the decocked re-usable biopsy gun shall be closed and the needle's protective sheath can be removed. By pulling the lever twice the device is ready for use and can be approached to the biopsy site – as a last step before triggering the safety lock has to switch from "locked" to "unlocked". Then introduce the needle under imaging control through the incision until the needle point is proximal to the area to be biopsied. When the position is confirmed the energized Möller Medical Blue RBG biopsy instrument hast to be triggered. Therefor the trigger button has to be depressed to cause both the stylet and cannula to automatically advance. Then the instrument has to be removed from the patient and the core tissue sample has to be exposed by pulling back the lever once from the side-notch. If additional biopsies are not being taken the used needle has

to be removed from the decocked biopsy gun and discarded.

Bone Marrow Biopsy System (BOW-1060), Bone Marrow Aspiration Biopsy (BOW-1070) and Bone Biopsy Needles (BOY-1080):

The purpose of the Bone Marrow Biopsy System, Bone Marrow Aspiration Biopsy and Bone Biopsy Needles is the harvesting of bone and bone marrow specimens. Access to the bone or bone marrow is achieved manually under the support of the devices cutting edge. Harvesting of bone or bone marrow specimens is accomplished manually and if required by aspirating which a syringe which is adapted to the Luer-Lock connector located at the handle of the cannula. Specimens are collected within the outer cannula which finally will be withdrawn from the patient. The needle has to be inserted by a qualified physician under imaging guidance such as CT.

Fine Needle Biopsy (FNB-xxxx):

The Fine Needle Biopsy is used for the percutaneous withdrawal of mainly cytological evidence of soft tissue for example from pleura cavity and associated organs, abdominal cavity and associated organs. For aspiration a Luer-Lock adapter is attached on the top of the Needle to connect a syringe. The needle has to be inserted by a qualified physician under imaging guidance such as Ultrasound.

Disposable Needles for Biopsy Gun (DNG-1010, -1020, -1030, -1040):

The Disposable Needles for Biopsy Gun are used for obtaining core biopsies of various tissues like lung, kidney, liver, prostate, abdominal soft tissue masses and breast. The needles are used in combination with different automatic biopsy guns and can be used with a corresponding coaxial needle for multiple sampling.The needle has to be inserted by a qualified physician under imaging guidance such as Ultrasound or CT.

Full-sCore® Biopsy Needle (DNG-2020):

The full-sCore® Biopsy Needle is used for biopsies of soft tissue in combination with the Möller Medical Blue. These biopsy needles are composed of a double-lumen cannula tube with bevelled edge tip cut; a trokar stylet is located inside the larger lumen. The stylet also has a polished tip. The smaller lumen contains a lengthwise spade, which works as a cutting mechanisms for the tissue collected inside the needle. Full-sCore® can be used with a corresponding coaxial needle for multiple sampling. The needle has to be inserted by a qualified physician under imaging guidance such as Ultrasound or CT.

Semi-automatic Biopsy Gun (SBG-xxxx):

The intended purpose of the disposable Semi-automatic Biopsy Gun is to obtain histological core samples from soft tissue such as liver, kidney, prostate, breast, lung and various soft tissue lesions. SBG-2010 is composed of an spring loaded biopsy needle fitted into a plastic handle permitting single handed specimen collection. The placement of the needle may be visualized by imaging guidance. SGB can be used with a corresponding coaxial needle for multiple sampling.The needle has to be inserted by a qualified physician under imaging guidance such as Ultrasound or CT.

Automatic Biopsy Gun (ABG-xxxx):

The intended purpose of the disposable Automatic Biopsy Gun of Möller Medical is to obtain core samples for valuable histological evidence from soft tissue such as liver, kidney, prostate, breast, lung and various soft tissue lesions. ABG can be used with a corresponding coaxial needle for multiple sampling. The needle has to be inserted by a qualified physician under imaging guidance such as Ultrasound or CT.

Coaxial Needles (COX-xxx):

If several biopsy specimens have to be taken from the same target area, the biopsies can be performed by means of several direct punctures or by using the coaxial technique. When performing direct punctures each and every time the biopsy needle or system has to be interseted into the patient. If a guiding needle is used together with the biopsy needle or system, this is known as coaxial approach. With this technique, only a single puncture is necessary. The guiding needle, the Coaxial Needle, is placed towards the suspicious area. Once the the coaxial needle is in place several biopsies can be performed by the biopsy needle or systems using the COX-xxxx as a guiding needle resp. as an introducer needle. It should be noted, that the guiding needle (COX) has to have a larger total diameter than the corresbonding biopsy needle or system and has to be shorter in length. The needle has to be inserted by a qualified physician under imaging guidance such as Ultrasound or CT.

Manual Cut Biopsy (MBY-xxxx):

The Manual Cut Biopsy needle is a manual biopsy needle for the evidence of histological tissue specimen. As with ABG, SBG and DNG the tru-cut technique is used in MBY. The needle has to be inserted by a qualified physician under imaging guidance such as Ultrasound or CT.

5. Indications for Use

The Möller Medical Biopsy Needles and Systems are used to obtain core samples and aspiration from tissue by biopsy. The various wall thicknesses, diameters, tip geometries and cutting techniques of the different hollow needle types and biopsy systems affect the quality of the biopsy specimen.

Model BOW-1060 bone marrow biopsy systems are intended for the atraumatic taking of specimens from and inside bones. Application areas of the products are bone respectively bone marrow.

Model BOW-1070 bone marrow aspiration biopsy set is intended for aspiration in the area of the sternum or iliac crest. Application areas of the products are bone respectively bone marrow.

Model BOY-1080 bone biopsy needle set has been designed for atraumatic bone biopsy. Application areas of the products are bone respectively bone marrow.

Model DNG-10XX single-use biopsy needles are exclusively intended for hollow needle biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions and are combined with biopsy guns.

Model full-sCore® DNG-2020 disposable biopsy needles are intended only for biopsies on soft tissue and tissue from soft, internal organs such as liver, kidney, breast, lung and various

soft tissue lesions , and should be used with the Möller Medical Blue (RBG-1000-10-1000) biopsy gun.

Model FNB and MBY single-use biopsy needles are exclusively intended for hollow needle biopsies of soft tissue for example from pleura cavity and associated organs, abdominal cavity and associated organs like breast, liver, prostate and kidney.

Model COX is for safe needle guidance and for taking several biopsy specimens, for example from liver, kidney, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions, with only one single puncture.

Model ABG disposable automatic biopsy guns are intended for biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions.

Model SBG disposable semiautomatic biopsy guns are intended for biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions.

Model Möller Medical Blue RBG is a reusable, automatic biopsy gun that is intended exclusively for use with DNG-1020 / full-sCore® DNG-2020 disposable needles for core needle biopsies of soft tissue such as liver, kidney, prostate, breast, thyroid, pancreas, spleen, lung and various soft tissue lesions.

When used for breast biopsy, the product is for diagnosis only. The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality; e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal of using standard surgical procedures.

6. Comparison of Technological Characteristics with the Predicate Devices

The BiopC Portfolio is working equivalently to the predicate devices. The principles of biopsy are exactly the same.

With exception of the Möller Medical Blue RBG Biopsy gun the products are for single-use like the appropriate predicate devices.

The BiopC Portfolio and its predicate devices are sold sterile with exception of the Möller Medical Blue RBG which is suitable for reprocessing like the appropriate predicate device.

The indication for use of the BiopC Portfolio is comparable with the indication for use of the predicate devices.

7. Performance Data

The BiopC Portfolio has the same indication for use and performance as the predicate devices. In addition, the BiopC Portfolio is made from the same materials with patient contact as the predicate devices. Because of this, no new safety or effectiveness are introduces over the predicate devices. Please refer to Table 2 for the list of bench tests – there you find a list of all bench tests that have been performed. Other products of the BiopC Portfolio can be subordinated to the bench tests of the single products.

The test series exhibits a very wide range of performance tests and all necessary and required tests for the BiopC Portfolio were appropriate performed and all tests passed according to the predetermined pass/fail criteria.

Table 2: List of bench test

Test	Tested Products	Test method summary	
Intensity Test	RBG	Test for preclearance of the Biopsy Gun	✓
Shelf Life	DNG	Test of tensile strength, impact strength and functionality after 5 years	✓
Artificial Ageing	DNG	Comparison new- 2 years - 5 years	✓
Firing Test	DNG	Firing test with Biopsy Gun	✓
Validation/Verification	DNG	Firing test with smallest widening tolerance	✓
Firing test	DNG	Test of minimum pull-out force	✓
Functionality test	DNG-2020	Function after 50 insertions per needle	✓
Performance test	All needles	Comparison of the general function, penetration characteristics, tissue sample size and mechanical durability of the different needles with the predicate devices	✓

8. Conclusion

The BiopC Portfolio is equivalent to the predicate devices in that:

- The devices have the same intended use and indication for use.
- The devices have equivalent design, function and areas of application
- The devices demonstrate equivalent performance.