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

October 27, 2016

M.D.L. S.r.l.
% Ms. Barbara Barbeau
Regulatory Consultant
Vantage Consulting International, Ltd.
888 E Belvidere Rd, Suite 212
Grayslake, Illinois 60030

Re: K160316
Trade/Device Name: SemiCut Semi-automatic Biopsy Needle, Themy Automatic Disposable Biopsy Device, Palium Automatic Reusable Biopsy Device, EasyCut Semi-automatic Biopsy Needle, MDL Biopsy and Coaxial Introducer Needles
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: September 23, 2016
Received: September 26, 2016

Dear Ms. Barbeau:

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 -A

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)*
K160316

Device Name
M.D.L. S.r.l. Soft Tissue Biopsy Devices and Accessories: SemiCut Semi-automatic Biopsy Needle, Themy Automatic Disposable Biopsy Device, Palium Automatic Reusable Biopsy Device, EasyCut Semi-automatic Biopsy Needle, MDL Biopsy and Coaxial Introducer Needles

Indications for Use *(Describe)*

• SemiCut Semi-Automatic Biopsy Needle is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.

• Themy Automatic Biopsy Needle is intended for obtaining core biopsy samples from soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone.

Themy Automatic Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the abnormality.

• Palium Automatic Reusable Biopsy Device is intended for use in obtaining core biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors. The device is not intended for use in bone.

• EasyCut Semi-Automatic Biopsy Needle is intended for soft tissue biopsy or aspiration. The device is not intended for use in bone.

• MDL Biopsy Needle is intended for soft tissue core biopsy with Palium Reusable Automatic Biopsy Device. The device is not intended for use in bone.

• Coaxial Introducer Needle is intended for use with biopsy devices cannula during soft tissue core biopsy procedures. The device is not intended for use in bone.

The extent of histological abnormality cannot be reliably determined from it 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 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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5.1. 510(k) Summary

In accordance with 21 CFR 807.92, the following summary of information is provided.

Date:	October 27, 2016
Device Owner:	M.D.L. S.r.l. Via Tavani 1/a 23014 – Delebio (So) - Italy
Company Contact:	Dr. Marcello Dell'Oca Chief Executive Officer +39 (0342) 68213
Device Name:	**Common Name:** Biopsy Devices and Accessories **Proprietary Names:** M.D.L. S.r.l. Soft Tissue Biopsy Devices and Accessories: SemiCut Semi-Automatic Biopsy Needle, Themy Automatic Disposable Biopsy Device, Palium Automatic Reusable Biopsy Device, EasyCut Semi-Automatic Biopsy Needle, MDL Biopsy Needles for use with Palium Automatic Reusable Biopsy Device and Coaxial Introducer Needles **Classification Name:** Gastroenterology-urology biopsy instrument **Regulation Number:** 21 CFR 876.1075 **Regulatory Class:** Class II **Device Panel:** 78 Gastroenterology/Urology **Product Code:** KNW, FCG

Predicate Devices:	**510k Number**
Bard® MAGNUM® Reusable Core Biopsy Instrument	K934371
Carefusion Temno Semi-Automatic Disposable Biopsy Instrument	K960064
Carefusion Achieve Automatic Biopsy System	K141552
H.S. Hospital Service Biomol Aspiration Biopsy Needle	K002947

5.2 Device Description

The M.D.L. S.r.l. Soft Tissues Biopsy Devices and Accessories include semi-automatic and automatic spring powered guns (disposable and reusable). Biopsy needle and cannula accessories are provided in a variety of sizes, designed to work with the manufacturer's semi-automatic and automatic guns to obtain and deliver a soft tissue core or aspirate sample, facilitate skin and tissue penetration, sample retention

and / or expulsion depending on the sample sites. The following biopsy devices are included in this submission for M.D.L. S.r.l. Soft Tissue Biopsy Devices and Accessories [Table 1].

Table 1 Soft Tissue Biopsy Devices and Accessories

Product Name	Product Description
Biopsy Devices	
SemiCut Semi-Automatic Biopsy Needle	Disposable, semi-automatic soft tissue core biopsy device
Themy Automatic Disposable Biopsy Device	Disposable, automatic device for core biopsy of soft tissue
Palium Automatic Reusable Biopsy Device	Reusable, automatic gun for core biopsy of soft tissue
EasyCut Semi-Automatic Biopsy Needle	Syringe style disposable, semi-automatic soft tissue core biopsy or fine needle aspiration (FNA) needle
Biopsy Device Accessories: Needles and Cannulas	
MDL Biopsy Needles for use with Palium Automatic Reusable Biopsy Device	Soft tissue core biopsy needles, disposable, for use with automatic guns
INTRO Coaxial Introducer Needles	Disposable needles for introduction of cannula, or biopsy devices

5.2.1. Device Format

The device format consists of several configurations: individually packaged sterile devices, co-packaged with various sterile compatible cannulas or introducer needles in disposable packaging materials or bulk packaged needles in various sized medical grade plastic blister pouches. These devices includes automatic guns (disposable or reusable design) packaged individually, or provided with compatible cannulas or needles. The packaging is compatible with the product's EO sterilization method.

5.3. Statement of Intended Use

The M.D.L. S.r.l. Soft Tissue Biopsy Devices and Accessories consist of SemiCut Semi-Automatic Biopsy Needle, Themy Automatic Disposable Biopsy Device, Palium Automatic Reusable Biopsy Device, EasyCut Semi-Automatic Biopsy Needle, MDL Biopsy Needles for use with the Palium Automatic Reusable Biopsy Device and Coaxial Introducer Needles. These devices are indicated for use as follows:

- **SemiCut Semi-Automatic Biopsy Needle** is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.

- **Themy Automatic Biopsy Needle** is intended for obtaining core biopsy from samples soft tissues such as kidney, liver, prostate and various soft tissue masses. The device is not intended for use in bone.

  Themy Automatic Biopsy Needle is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the abnormality.

- **Palium Automatic Reusable Biopsy Device** is intended for use in obtaining core biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors. The device is not intended for use in bone.

- **EasyCut Semi-Automatic Biopsy Needle** is intended for soft tissue biopsy or aspiration. The device is not intended for use in bone.

  The extent of histological abnormality cannot be reliably determined from it 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 using standard surgical procedures.

MDL Accessories

- The **MDL Biopsy Needle** is intended for soft tissue core biopsy with Palium Reusable Automatic Biopsy Device. The device is not intended for use in bone.
- **Coaxial Introducer Needle** is intended for use with biopsy devices and cannula during soft tissue core biopsy procedures. The device is not intended for use in bone.

  The extent of histological abnormality cannot be reliably determined from it 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 using standard surgical procedures.

5.4 Technological Characteristics and Indications

The M.D.L. S.r.l. Soft Tissue Biopsy Devices are designed and constructed similar to, or the same as the predicate devices for intended use, device format, design features for gauge, needle length, sampling notch, mechanism of action and operating principles, described below **(5.4.1 and 5.4.2**) for Core Needle Biopsy and Fine Needle Aspiration Procedures.

5.4.1 Core Needle Biopsy Procedures

In procedures where an automatic gun is used, the disposable needles and cannula are loaded and the gun is activated by the user. For the MDL automatic and semi-automatic devices, the cannula is designed with an outer cutting cannula having a sharpened tip and an inner stylet with sample slot. Depending on the device mechanism of action, the cannulas are advanced simultaneously or sequentially into the tissue for samples.

The stylet with sample notch extends forward cutting the tissue. A tissue specimen is retained within the sample notch until it is withdrawn and retrieved. The biopsy needle may also be advanced using with an introducer cannula positioned within tissue to provide support where needed for repeated samplings.

5.4.2. Fine Needle Aspiration (FNA) Procedure

For the fine needle aspiration biopsy device, the user manually guides the cannula and the inner stylet to penetrate the tissue. Once tissue penetration is obtained, the tissue is aspirated into the cannula facilitated by the vacuum which is transmitted from the integral syringe barrel.

5.5. Subject Device vs. Predicate Device

M.D.L. S.r.l. Soft Tissue Biopsy Devices share many similarities with the predicate biopsy devices, including intended use, anatomical sites, mechanism of action and design features. The sterilization method, biocompatibility, and performance testing support suitability of each device for its intended purpose and substantial equivalence of the new MDL biopsy devices compared to their predicate devices.

5.5.1. Disposable Biopsy Devices

Device Format: The subject disposable biopsy devices share the same format as the predicate devices for sterile, single use, and EO compatible packaging. Results from device testing indicate that subject devices are non-pyrogenic.

Needle Design: The disposable biopsy device needle designs display minor differences between the subject device and the predicate devices for gauge and needle length. However, Themy and SemiCut provide two slot sizes, 10 mm and 20 mm compared to 20 mm their predicate devices.

SemiCut and Themy cannulas are designed with ultra-sharp stylet tip with Menghini sampling notch compared to their predicate device with trocar stylet tips. EasyCut and predicate device cannulas are similar: an ultra-sharp triple tip stylet and Tru-Cut needle with guillotine (Menghini tip) versus the predicate with pyramidal stylet tip and Menghini type needle.

Needle Advancement and Tissue Access: SemiCut has the same functionality as the predicate device. The devices provide a single or two-stage (sequential) automatic stylet advancement with different needle designs. The subject and predicate device differ in sample capture. The subject device is differentiated with a Menghini sampling notch with a guillotine sample capture (new device) vs trocar stylet and

cannula (predicate), and a stylet that provides tissue piercing access to site (new device) vs clinician skin puncture (predicate).

Themy with guillotine coring and the predicate device with cannula coring provide the clinician with the same single or two-stage (sequential) automatic advancement for fixed sample length for tissue penetration and cutting.

EasyCut and predicate device provide similar tissue access and sample aspiration using Menghini sampling technique, however the EasyCut stylet provides tissue piercing access to the site (new device) vs clinician skin puncture (predicate).

Mechanism of Action: The mechanism of action for EasyCut and SemiCut compared to the predicate devices are the same; single-hand semi-automatic activation; Themy has the same single-hand automatic activation as its predicate.

Usability and Convenience: Both the subject disposable devices and the predicate devices provide design features that facilitate clinician use during biopsies: cannula centimeter marks, echogenic radiographic visibility, color coded needle hubs, and adjustable depth stops.

Materials of Construction: The subject disposable devices are constructed of AISI 304 SS and medical grade plastics which met Biocompatibility requirements per ISO10993.

5.5.2. Reusable M.D.L. Biopsy Devices

Device Format: Palium shares the same format as the predicate device for nonsterile, reusable features. Palium is used with disposable biopsy needles supplied by the manufacturer and provides the same penetration depth as the predicate device, 15 mm and 22mm.

Design Features: Both Palium and the predicate device provide penetration depth control by lever selection on device housing. Palium provides a sequential advancement system compared to the single stage advancement of the predicate device. Each device is sterilizable with cleaning and steam sterilization methods provided in the IFU.

Mechanism of Action: Palium and the predicate device differ in the mechanism of action feature. The subject device provides a one stage or two stage firing mode (user preference) compared to the single stage fixed firing mode of the predicate device.

Materials of Construction: Palium is constructed of AISI 304 SS and medical grade plastics which met Biocompatibility requirements per ISO10993.

6. Performance Testing (Bench)

6.1 Biocompatibility, Pyrogenicity and Sterility

The M.D.L. Biopsy Devices met the biocompatibility standard for Cytotoxicity ISO 10993-5, Delayed Hypersensitivity or Sensitization ISO 10993-10, Intracutaneous Reactivity ISO 10993-10, Acute Systemic Toxicity ISO 10993-11, and Hemolysis ISO 10993-4.

The devices met the requirements for non-pyrogenicity per Pyrogen Test USP<151>, Bacterial Endotoxins Test USP<85>. Sterilization was validated per ISO11135, and residuals for ETO, EG and ECH met ISO10993-7.

6.2. Device Shelf-life

The subject devices in their packaging were subjected to accelerated aging to simulate a 5 year shelf life (Treatment: 60°C, 28 days, <50% RH). Three lots of aged and non-aged subject devices were tested in triplicate for Mechanical Durability, Depth Projection, Device Needle Penetration, Activation Force (Spring Force) and Extraction to assess the impact of simulated aging on the device performance. Visual Appearance inspection for Metal Oxidation, Plastic Coloration, Plastic Integrity (cracks, damage) indicated that there no aesthetic, or design changes for the aged devices. Performance testing results of the aged devices was unchanged compared to untreated (non-aged) device.

6.3 Performance Testing

Samples of each device product family (subject device) were selected at the extremes of device design for needle length and gauge sizes for comparative testing to predicate devices for device performance.

Depth Projection: Subject devices vs. predicate devices testing for Depth Projection measured the needle advancement during activation. Cannula needle advancement must meet a distance of ≥ 20mm compared to the notch. The results showed that subject devices tested side-by-side with predicate devices were comparable over 50 shots per use and met criteria: Needle Advancement > 20 mm.

Penetration Force: Subject devices vs. predicate devices for Penetration Force was assessed using ASTM F3014 guidance. Simulation of biological tissues using a certified testing foil was used in the Dynamometer setup. Each tested subject and predicate device was activated 50 times to replicate the maximum number of biopsy shots performed during a medical procedure. The results showed that the subject devices required less force compared to the predicate devices and met the criteria: Penetration Force $_{(FMDL)} < F_{(Predicate)}$.

Activation Force: Subject and predicate device testing for Spring Force was measured during device activation. The results showed the subject devices tested side-by-side with predicate devices were comparable over 50 shots per use and met criteria: Spring Force $_{(FMDL)} > F_{Predicate}$.

Mechanical Durability: Subject and predicate device testing for Mechanical Durability was performed in two parts: breaking force and detachment force. Device cannulas subjected to progressive force determined the breaking force. The detachment force test determined the point at which the plastic components sever from the device point of attachment. Results showed that subject devices in comparison to the predicate device met the criteria, Breakage Force $_{(FMDL)} > F_{Predicate}$, and Detachment of Components: Does Not Occur.

Extraction Testing: Subject and predicate devices testing for Sample Extraction quantitatively evaluated extraction capacity of subject devices compared with predicate devices. The results showed that the subject devices tested side-by-side with predicate devices were comparable over 50 shots per use for Palium compared to the predicate device. EasyCut, SemiCut and Themy devices produced slightly larger samples by weight compared to predicate device at 50 shots per use.

Table 2 Performance Testing Summary

Performance Testing	Device Name			
	SemiCut	**EasyCut**	**Themy**	**Palium**
Biocompatibility per ISO10993	Meets	Meets	Meets	Meets
Pyrogen Test USP per <151> **Bacterial Endotoxins Test USP per <85>**	Meets	Meets	Meets	N/A*
Residual ETO, ECH[§], EG[§] per ISO10993-7	Meets	Meets	Meets	N/A*
Sterile per ISO 11135	Meets	Meets	Meets	N/A*
Mechanism Performance				
• **Depth Projection [(1)]**	Similar**	N/A	Similar	Similar
• **Mechanical - Durability [(2)]**	Similar	Similar	Similar	Similar
• **Penetration [(3)]**	(a)	Pass	Pass	Pass
• **Activation Force (Spring) [(4)]**	Pass**	Pass	Pass	Pass
• **Extraction [(5)]**	***	***	***	Pass

* Nonsterile device, ** 20 mm Slot, ***Statistically Sig. Diff. (MDL Sample Wt. > Predicate Sample Wt.)

§ Below limit of quantitation (1 mg/device)

N/A/ not applicable (design), (a) Same Needle as Themy

Criteria: (1) Cannula Advancement $\geq$ 20 mm = Pass; (2) Breakage Force (F_{MDL}) $\geq F_{Predicate}$ and Detachment of Components does not occur; (3) Penetration Force (F_{MDL}) $\leq F_{Predicate}$; (4) Activation Force (F_{MDL}) $\leq F_{Predicate;}$ (5) MDL Non-statistically Significant Different to Predicate

5.7 Conclusion

The analysis of the M.D.L. Soft Tissue Biopsy Devices by intended use, indications, anatomical locations, and mechanism of action supports that the subject devices are the same as those of the predicate devices.

The disposable subject device varied primarily from the predicate devices in the needle design providing different slot sizes for sample capture and Menghini sampling notch compared to predicate device cannulas with trocar stylet tip (SemiCut, Themy). Tissue penetration differs between subject and predicate (SemiCut and Easy); subject devices are designed with a stylet that provides tissue piercing access to site without clinician skin puncture. Needle advancement for the subject (Themy) device provides a single or two-stage (sequential) automatic advancement for fixed sample length for tissue penetration and cutting compared to the predicate single stage advancement mechanism.

Materials of construction are those commonly used in medical devices and met biocompatibility requirements for medical devices. The sterile disposable devices also met the requirements for non-pyrogenicity and sterility per ISO and USP standards.

Samples of each device were selected at the extremes of needle length and gauge for comparative device performance testing. The results of the subject device performance for Penetration, Depth Projection, Mechanical Durability and Activation Force are comparable to the predicate devices. Sample Extraction results were consistent between Palium and its predicate device. However, SemiCut, EasyCut and Themy provided sample weights on average that were slightly greater than the predicates. The difference in sample extraction is due to small differences in designs for cannula and sample slots, i.e. Menghini sampling notch with a guillotine sample capture.

Performance testing for the MDL devices supports a single disposable device activation of 50 shots per use. A 5-year shelf life for the disposable MDL devices is supported based on accelerated aging studies for device and packaging.

The M.D.L product labeling, instructions for use, and the reusable device cleaning and sterilization IFU support the safety and effectiveness of the M.D.L. S.r.l. Soft Tissue Biopsy Devices for their intended uses. There are no new questions concerning the safety and effectiveness of these devices.