Medimetrix, LLC
% Christine Scifert
Partner
MRC Global
9160 Hwy. 64, Suite 12
P.O. Box 330
Lakeland, Tennessee 38002

August 4, 2026

Re: K260572
Trade/Device Name: Marrow Marxman
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 6, 2026
Received: July 6, 2026

Dear Christine Scifert:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.08.04 16:04:24 -04'00'

Colin Kejing Chen, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260572

Device Name
Marrow Marxman

Indications for Use *(Describe)*
The Marrow Marxman is intended for aspiration of bone marrow or autologous blood using a standard piston syringe.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Marrow Marxman
31 July 2026

Company: Medimetrix LLC
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Primary Contact: Christine Scifert – Partner
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Company/Secondary Contact: Brian Austin
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Managing Member
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brian@austinmedco.com

Trade Name: Marrow Marxman

Common Name: Instrument, Biopsy

Classification: Class II

Regulation: 21 CFR 876.1075 – Gastroenterology-urology biopsy instrument

Panel: Gastroenterology & Urology

Product Code: KNW

Primary Predicate: Ranfac Lateral Access Bone Marrow Aspiration Needle – K223612

Device Description:

The Marrow Marxman is a manual, sterile disposable flexible cannula intended for the purposes of aspirating bone marrow or autologous blood. The device consists of a flexible shaft with trocar installed, pusher rod for removing clogs, and a 4.75mm drill with depth stop. The Marrow Marxman flexible cannula with sharp tip and trocar installed penetrates bone and bone marrow with the aspirate obtained through the flexible cannula after the trocar is removed.

Once the flexible cannula is properly positioned and the trocar removed, the aspiration cannula has a flexible shaft which will redirect if the tip encounters the wall of the marrow cavity.

A 4.75mm drill with depth stop is provided for use with the device which can mate to a standard surgical drill to aid bone penetration if needed.

Indications for Use:

The Marrow Marxman is intended for aspiration of bone marrow or autologous blood using a standard piston syringe.

Substantial Equivalence:

The subject Marrow Marxman substantial equivalence was evaluated to the following predicate devices:

Primary Predicate:

- Ranfac Lateral Access Bone Marrow Aspiration Needle (CRVS-BMA-LA) (Ranfac Corporation) – K223612

Additional Predicate Devices:

- Marrow Cellution Bone Marrow Aspiration Needle (Ranfac Corporation) – K150563
- Ran-Flex B Bone Marrow Aspiration Needle (Ranfac Corporation) – K202287
- Ranfac Bone Marrow Aspiration Needle (Ranfac Corporation) – K131157

There are insignificant differences between the subject Marrow Marxman and the predicate devices. The Indications for Use are identical to that of the predicate and additional predicate devices, as all are indicated for “aspiration of bone marrow or autologous blood using a standard piston syringe.”

The patient contacting portions of the subject and predicate devices are all manufactured from stainless steel.

The subject device has a slightly larger diameter (5.0mm) than that of the predicate devices (2.11mm – 4.6mm), but simulated use has shown similar performance when compared to the predicates.

The insertable length (12.5cm) of the subject device falls within the range of the predicate devices (3 – 25cm).

The design of the subject device has many similar features when compared to the predicate devices. Similarly, the function of the subject device is equivalent to the Ran-Flex B device in its ability to flex and “redirect if the tip encounters the wall of the marrow cavity.” Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Biocompatibility testing including cytotoxicity per ISO 10993-5, sensitization per ISO 10993-10, irritation per ISO 10993-10, systemic toxicity per ISO 10993-11, and material mediated pyrogenicity per ISO 10993-11 has been performed and determined that the subject device is non-cytotoxic, non-sensitizing, non-irritant, non-systemically toxic following acute exposure, and non-pyrogenic.

Torque and bending tests have been conducted on the subject device, in addition to simulated use comparison to the predicate. Testing and simulated use have confirmed that the proposed design changes do not raise new issues of safety and effectiveness.

Conclusion:

Based on the specifications and performance comparison to the predicate device, the subject device is determined to be substantially equivalent in terms of safety and effectiveness to the predicate device for the requested indications for use.