



September 30, 2025

FEHLING Instruments GmbH
Imad Ziate
Quality Management
Hanauer Landstr. 7A
Karlstein, Bavaria 63791
Germany

Re: K252722

Trade/Device Name: Biopsy Forceps
Regulation Number: 21 CFR 870.4075
Regulation Name: Endomyocardial Biopsy Device
Regulatory Class: Class II
Product Code: DWZ
Dated: August 28, 2025
Received: August 28, 2025

Dear Imad Ziate:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Samuel G. Raben -S

Samuel Raben, PhD
Assistant Director (Acting)
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K252722

Device Name

Biopsy Forceps

Indications for Use (Describe)

FEHLING Biopsy Forceps are used to obtain endomyocardial biopsy specimens from the right and left ventricle via percutaneous arterial or venous approach.

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.

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510(k) #: K252722

510(k) Summary

Prepared on: 2025-09-15

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	FEHLING Instruments GmbH
Applicant Address	Hanauer Landstr. 7A Karlstein Bavaria 63791 Germany
Applicant Contact Telephone	+4906188957429
Applicant Contact	Mr. Imad Ziate
Applicant Contact Email	imad_ziate@fehling-instruments.de

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Biopsy Forceps
Common Name	Endomyocardial biopsy device
Classification Name	Device, Biopsy, Endomyocardial
Regulation Number	870.4075
Product Code(s)	DWZ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K170726	Biopsy Forceps	DWZ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Biopsy Forceps are designed to allow percutaneous access to the right or left ventricles of the heart to obtain diagnostic tissue samples. The forceps consist of three main components:

1. an actuating handle ergonomically designed for comfortable use,
2. a flexible shaft,
3. and surgical stainless steel cutting jaws.

At the distal end of the forceps is a pair of stainless steel jaws used to obtain the tissue samples. At the proximately end of the forceps is the actuation handle used to activate the jaws and steer the device.

The product is provided single for use and sterile.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

FEHLING Biopsy Forceps are used to obtain endomyocardial biopsy specimens from the right and left ventricle via percutaneous arterial or venous approach.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same as the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The design and principle of operation of the device are identical to those of the predicate device. The material of components was changed to similar materials. All other materials and technological aspects are identical.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

There was no clinical testing required to support the medical device. No additional non-clinical testing was required as the modifications to the device did not require any testing.