DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 2, 2017

Fehling Instruments GmbH & Co. KG
% Arne Briest
CEO
VISAMED GmbH
Kastellstr. 8
D-76227 Karlsruhe
Germany

Re: K170726
Trade/Device Name: Biopsy Forceps
Regulation Number: 21 CFR 870.4075
Regulation Name: Endomyocardial Biopsy Device
Regulatory Class: Class II
Product Code: DWZ
Dated: March 6, 2017
Received: March 9, 2017

Dear Mr. Briest:

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K170726

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

1. Submission Sponsor and Application Correspondent

A. Submission Sponsor

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Contact:	Mr. Arne Briest

2. Date Prepared

Date Prepared: May 15, 2017

3. Device Identification

Trade/Proprietary Name:	Biopsy Forceps
Device:	Device, Biopsy, Endomyocardial
Regulation Description:	Endomyocardial biopsy device
Classification Regulation	21 CFR 870.4075
Product Code:	DWZ
Device Class:	Class 2
Classification Panel	Cardiovascular

4. Legally Marketed Predicate Devices

Primary Predicate:
K973818 – Boston Scientific Corporation Northwest Technology Center, Inc.; T-REX ™- Biopsy foreceps, cleared December 16, 1997

Additional Predicate:
K881412 – Fehling Medizintechnik GmbH, Myocard Biopsy Forcep, cleared September 8, 1988

5. Device Description

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.

6. Indications for Use

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

7. Substantial Equivalence Discussion

The Biopsy Forceps have the same intended use, similar performance characteristics, are manufactured from similar materials and are similar in design to the predicate devices.

The Biopsy Forceps are identical in design, material and intended to the previously cleared Biopsy Forceps by Fehling.

	Biopsy Forceps (subject device)	**MYOCARD BIOPSY FORCEP**	**T-REX™ Biopsy**	**Substantial Equivalence**
510k Reference	(subject device)	K881412	K973818	-
Product Code	DWZ	DWZ	DWZ	Identical
Regulation #	870.4075	870.4075	870.4075	Identical
Class	II	II	II	Identical

	Biopsy Forceps Bioptome (subject device)	MYOCARD BIOPSY FORCEP	T-REX™ Biopsy	Substantial Equivalence
Manufacturer	FEHLING INSTRUMENTS GmbH & Co. KG	FEHLING INSTRUMENTS GmbH & Co. KG	Boston Scientific Corporation Northwest Technology Center, Inc.	-
Indication for Use	FEHLING biopsy forceps are used to obtain endomyocardial biopsy specimens from the right and left ventricle via percutaneous arterial or venous approach.	The Fehling Myocardial Biopsy Forceps are intended for use in ventricular endomyocardial biopsy	The T-REX biopsy forceps is used to obtain endomyocardial biopsy specimens from the right and left ventricle via percutaneous arterial or venous approach.	Similar
Sterility	Sterile	Sterile	Sterile	Identical
Sterilization	ETO, SAL 10^{-6}	ETO, SAL 10^{-6}	ETO, SAL 10^{-6}	Identical
Utility	Single Use	Single Use	Single Use	Identical
End-Effector and Jaw Assembly				
Jaws	Proprietary sharpening method	Proprietary sharpening method	Proprietary sharpening method	Identical
Actuator links	Hardened stainless steel	Hardened stainless steel	Hardened stainless steel	Identical
Actuator/ pull wire connection	Laser Welded	Laser Welded	Laser Welded	Identical
Housing	Slotted jacket	Slotted jacket	Laser welded housing halves	Similar
Housing to outer Jacket Connection	Laser Welded	Laser Welded	Laser welded	Identical
Crank length / lever angle	1.6mm jaws; 1.8mm jaws; 2.2mm jaws;	1.6mm jaws; 1.8mm jaws; 2.2mm jaws;	1.8mm jaws; 2.2mm jaws; 15°	Similar
Length of Shaft	510 mm 800 mm 1000 mm 1200 mm	510 mm 800 mm 1000 mm 1200 mm	-	Identical (additional 1200 mm length offering for 2.2 mm jaws)
Attachment of actuator/ actuator links and jaws/housing	Captured by slotted jacket	Captured by slotted jacket	Captured by laser welded housing halves	Similar
Body				
Pull Wire	Solid Stainless Steel Wire	Solid Stainless Steel Wire	Solid Stainless Steel Wire	Identical
Shape	Flexible	Flexible	Flexible and pre-curved	Similar
Liner	---	---	Liner between outer jacket and pull wire	Identical

Jacket sheath	Jacket sheath covering the outer jacket	Jacket sheath covering the outer jacket	Jacket sheath covering the outer jacket	Similar
Handle Assembly				
Handle transition to outer jacket	Crimped joint with internal rope	Crimped joint with internal rope	Crimped joint with integral strain relief	Similar
Handle transition to handle body	Plastic handle transition press fit into tapered handle body	Plastic handle transition press fit into tapered handle body	Stainless steel handle transition press fit into tapered handle body	Similar
Finger Grip / Handle body	Pusher for holding jaws open during specimen	Pusher for holding jaws open during specimen	Locking feature for holding jaws open during specimen removal	Similar
Finger grip insert for attachment of pull wire	Plastic (POM)	Plastic (POM)	Aluminum / Press fit	Similar
Handle Spring	20mm coil spring	20mm coil spring	12,7 mm Spring coil	Similar
Package				
Configuration	Single Barrier	Single Barrier	Single Barrier	Similar
Product Holder	Blister Package	Blister Package	Coil or Card	Similar
Similar basic design and shape, fitting the indication, dimensions are adjusted accordingly				

8. Non-Clinical Performance Data

Biocompatibility

Biocompatibility testing on the Fehling-Biopsy Forceps was conducted and evaluated per ISO 10993-1.

Cytotoxicity
The full strength EMEM10 test article showed no cytotoxic potential to L-929 mouse fibroblast cells.

Chemical Characterization

The Biopsy Forceps, were exhaustively extracted in Purified Water, Ethanol, and Hexane. The resulting extracts were analyzed by Fourier Transform Infrared Spectroscopy (FTIR) and Gas Chromatography (GC-MS). The ethanol and hexane test extracts were analyzed by Ultra Performance Liquid Chromatography – Mass Spectroscopy (UPLC-MS). The purified water test extract was analyzed by Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES) and Ion Chromatography.

Conclusion:

The biological risk assessment performed was supported by information on the Biopsy Forceps materials of construction, gathered toxicological data on these materials, available chemical characterization and biological data on Biopsy Forceps. This information and related analysis provides the evidence required to conclude that additional biocompatibility testing is not needed. The Biopsy Forceps therefore meets the requirements of ISO 10993-1 and 2016 FDA Guidance for

externally communicating devices with limited contact (<24 hours) with circulating blood and can be considered biocompatible for use.

Non-Clinical Performance Testing

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Dimensional Verification Tests
Dimensional verification testing was performed to evaluate the Biopsy Forceps.

All samples passed the test and met the acceptance criteria.

Tensile Tests
Tensile Tests on critical joints were performed on the Biopsy Forceps to evaluate the mechanical stability of the product.

All samples passed the test and met the acceptance criteria.

Simulation Test – Insertion and Taking of Tissue Samples

The purpose of the test was to evaluate the introduction of the device to a worst case anatomical structure and to harvest tissue samples using fresh porcine heart specimens. The process was repeated 10 times per device.

All samples passed the test and met the acceptance criteria.

Shelf Life Testing and Transport Simulation

Shelf Life Testing and Transport Simulation testing was performed to support the shelf life of 5 years and the safe transport of the Biopsy Forceps.

All samples passed the test and met the acceptance criteria. The Biopsy Forceps have a shelf life of 5 years.

9. Clinical Performance Data

There was no clinical testing required to support the medical device.

10. Statement of Substantial Equivalence

The information presented in this 510(k) submission demonstrates that the differences between the Biopsy Forceps and the predicate devices do not raise any questions regarding safety and effectiveness.

Performance testing and compliance with voluntary standards demonstrate that the Fehling- Biopsy

Forceps are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.

The Biopsy Forceps are determined to be substantially equivalent to the referenced predicate devices.