April 20, 2023

Fehling Surgical Instruments, Inc.
% Jennifer Palinchik
President
Jalex Medical
27865 Clemens Rd Suite 3
Westlake, Ohio 44145

Re: K220981
Trade/Device Name: SUPERPLAST Double-Occluder, SUPERPLAST Vascular Probe
Regulation Number: 21 CFR 870.4475
Regulation Name: Surgical vessel dilator
Regulatory Class: Class II
Product Code: DWP
Dated: March 24, 2023
Received: March 24, 2023

Dear Jennifer Palinchik:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Carmen G. Johnson -S

Carmen Gacchina Johnson, PhD
Assistant Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220981

Device Name
SUPERPLAST Double-Occluder
SUPERPLAST Vascular Probe

Indications for Use *(Describe)*
The Fehling SUPERPLAST Probes are intended to be used to enlarge or calibrate vessels during coronary artery bypass and angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.

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.

510(k) Summary

Submitted By:	Fehling Surgical Instruments, Inc. 1690 Stone Village Lane STE 721 Kennesaw, GA 30152
Date:	April 18, 2023
Contact Person:	Jennifer Palinchik, President, JALEX Medical
Contact Telephone:	(440) 935-3282
Contact Fax:	(440) 933-7839
Device Trade Name:	SUPERPLAST Probes: SUPERPLAST Double-Occluder SUPERPLAST Vascular Probe
Common Name:	Vascular Dilator
Device Classification Name:	Dilator, Vessel, Surgical
CFR Section:	870.4475
Device Classification:	Class II
Reviewing Panel:	Cardiovascular
Product Code:	DWP
Predicate Device:	Geomed Vascular Dilators (K183438) The predicate device has never been subject to a recall.

Device Description:

The Fehling SUPERPLAST Probes are intended to be used to enlarge or calibrate vessels during coronary artery bypass and angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels and to perform various maneuvers of dilation and measurement of annulus and lumen diameters. The coronary probe is available in different lengths and diameters to accommodate the needs of various surgical procedures and vessel anatomies. The probe is constructed of Titanium Alloy (TiAl6V4), Nitinol, and Titanium (Grade 2). Coronary probes are supplied non-sterile.

Indications for Use:

The Fehling SUPERPLAST Probes are intended to be used to enlarge or calibrate vessels during coronary artery bypass and angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.

Summary of Technological Characteristics:

The Fehling SUPERPLAST Probes and the predicate have the same intended use and fundamental scientific technology. Both devices are similar in technological characteristics as noted in the table below.

Item	Fehling SUPERPLAST Probe	Geomed Vascular Dilators
Intended Use	Used to enlarge or calibrate vessels during coronary artery bypass and angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.	Used to enlarge or calibrate vessels during coronary artery bypass and angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.
Sterility	Provided Non-sterile	Provided Non-sterile
Reusable	Yes; single re-use	Yes; multiple re-use
Sterilization	Steam sterilized by user facility per validated procedure	Steam sterilized by user facility per validated procedure
Description	Reusable surgical instrument used to enlarge or calibrate vessels	Reusable surgical instrument used to enlarge or calibrate vessels
Materials	Titanium (handle) and Titanium Alloy (tip) conforming to ISO 5832, Nitinol (shaft) conforming to ASTM F2063	Stainless Steel
Design Features	Manual, non-electrical, non-sterile, reusable, malleable shaft	Manual, non-electrical, non-sterile, reusable, non-malleable
Patient contact	Blood vessels, transient (<15 min)	Blood vessels, transient (<15 min)
Tip Sizes	0.5-5mm	1.0-10mm
Lengths	8cm-21cm	14cm-19cm

Performance Testing:

Substantial equivalence is supported by the results of mechanical testing including tensile testing and simulated use testing. Preliminary data was collected to determine the force required to remove a probe

from a blood vessel. Tensile testing was conducted to demonstrate that the probes can handle the forces clinically required, and to determine at what point the probes break. Devices were tested to the point of failure on the worst-case configuration of the Fehling probes. In addition, probes are dimensionally verified.

Validation of the end user automated cleaning procedures, end user steam sterilization process, and drying time after sterilization was conducted. Cleaning and sterilization validation testing was conducted in accordance with the recommendations outline in FDA Guidance Document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (3/17/2015)"

Biocompatibility Testing:

Biocompatibility testing per ISO 10993-1 was performed for the following endpoints: cytotoxicity, irritation, sensitization, acute systemic toxicity, hemocompatibility, and pyrogenicity.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.