Seigla Medical, Inc.
Chad Kugler
President & CEO
7688 5th Street SE
Buffalo, Minnesota 55313

Re: K220691
Trade/Device Name: LiquID 061 Guide Catheter Extension, LiquID 071 Guide Catheter Extension
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 8, 2022
Received: March 9, 2022

Dear Chad Kugler:

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,

for Lydia Glaw, Ph.D.
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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)*
K220691

Device Name
Seigla Medical LiquID Guide Catheter Extension

Indications for Use *(Describe)*
The LiquID Guide Catheter Extension is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Date Prepared: 08 March 2022
510(k) Number: K220691

Legal Manufacturer:

Name:	Seigla Medical, Inc.
Address:	7688 5th St SE Buffalo, MN 55313
Email:	ckugler@seiglamedical.com
Contact Person:	Chad Kugler
Phone Number:	(763) 615-9058
Facsimile Number:	(612) 453-4774

Device Information:

Classification:	Class II Percutaneous Catheter / DQY / 870.1250
Trade Name:	Seigla Medical LiquID M Guide Catheter Extension
Common Name:	Catheter

Reference Devices:

The Seigla Medical Liquid Guide Catheter Extension is substantially equivalent in intended use, method of operation and technical aspects to the following predicate devices:

Primary Predicate:
K172090 - Vascular Solutions/Teleflex Guideliner V3 Catheters

Additional Reference Devices:
K163314 - Boston Scientific Guidezilla II Guide Extension Catheter
K183353 - Medtronic Telescope Guide Extension Catheter
K160561 - QX Medical Boosting Catheter

Summary Description:

The LiquID device is a guide catheter extension that is substantially equivalent to currently marketed devices with the distinction of having a larger intraluminal diameter. The device is available in two models: Liquid 061 and LiquID 071 which are designed to fit within 6F and 7F conventional guide catheters, respectively. The device has a 150 cm working length and a 0.018" diameter proximal stainless-steel shaft connected to a 15cm single lumen distal shaft (exchange length).

The LiquID device distal shaft includes an internal PTFE liner, a MP35N coil internally clad with a tantalum core for support and radiopacity, and an exterior nylon-based encapsulation layer. The rounded and atraumatic distal tip includes PTFE and Pebax that is monolithically attached (no joints) to the distal shaft. The distal shaft exterior is wiped with silicone fluid for lubricity.

The transition between the single lumen distal shaft and proximal shaft includes a stainless collar that is welded to the proximal shaft, positioned over the PTFE liner, and encapsulated in polymer. This construction provides a smooth transition and structural integrity.

The LiquID device has proximal positioning marks (laser created oxide marks) that are approximately 95cm and 105cm from the distal tip and has a colored proximal handle that follows the coronary guide catheter size color code. The proximal shaft is not coated.

The LiquID device is packaged in a HDPE hoop within a Tyvek poly sealed pouch. The pouch is contained in an SBS shelf box. Twenty-five (25) shelf boxes are contained within a shipping container. The shipping containers are used for transporting the devices between the manufacturer, the ethylene oxide (EO) sterilization contractor, and the distribution locations.

Indication for Use:

The LiquID Guide Catheter Extension is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

Comparison to Predicate Devices:

The LiquID Guide Catheter Extension is substantially equivalent to the Vascular Solutions/Teleflex Guideliner V3 Catheters (K172090). In addition, the Boston Scientific Guidezilla II Guide Extension Catheter (K163314), Medtronic Telescope Guide Extension Catheter (K183353) and the QX Medical Boosting Catheter (K160561) are included as reference devices.

Guide catheter extensions are designed to facilitate the placement of interventional devices. They are placed within the interior lumen and advanced beyond the distal tip of conventional guide catheters. These devices allow physicians to achieve deeper vascular intubation providing enhanced placement and support for subsequent interventional device delivery.

The LiquID device and, the predicate device, and the reference devices include a PTFE lined single lumen distal shaft that is metal (coil or braid) supported with an exterior polymer encapsulation layer. The device distal shafts have an exterior coating for lubricity and include radiopaque features. The devices transition from the distal shaft to a push rod with designs that allow the introduction of interventional devices from the guide catheter and into the device distal shaft. The device transitions are also designed for strength. The devices are EO sterilized and are conventionally packaged (hoop, pouch, and box).

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the Seigla LiquID Guide Catheter Extension device has been shown to be substantially equivalent to a currently marketed predicate device and reference devices.

1. The LiquID device has been verified through the following tests:

    - Shaft Marker Location and Visibility
    - Inside Diameter
    - Outside Diameter
    - Working Length
    - Exchange Length
    - Distal Tip Length
    - Device Preparation
    - Functionality with a Hemostasis Valve
    - Trackability
    - Contrast Injection
    - Compatibility with Interventional Devices
    - Radiopacity
    - Kink Resistance
    - Distal and Proximal Flexibility
    - Surface Inspection
    - Tensile and Torsional Strength
    - Push Rod to Attachment Bend
    - Burst Pressure
    - Corrosion Resistance
    - Coating Durability
    - Particulate Evaluation

2. The LiquID device passed the following biocompatibility tests performed in accordance with ISO 10993-1:

    - Cytotoxicity
    - Sensitization
    - Irritation
    - Systemic Toxicity
    - Pyrogenicity
    - ASTM Hemolysis
    - Complement Activation
    - Thrombogenicity

3. The LiquID device has been validated to meet a SAL of 10^{-6} in accordance with ISO 11135.

The results of these verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the LiquID device is a guide catheter extension that is substantially equivalent to the predicate devices.