April 4, 2025

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

Re: K243691
Trade/Device Name: LiquID .051 LP Guide Catheter Extension
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 25, 2024
Received: November 26, 2024

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 (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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.04.04 17:43:15 -04'00'

for Lydia Glaw
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243691

Device Name
LiquID 0.51 LP 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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510(k) Summary
[As required by 21 CFR 807.92]

Date Prepared: February 28, 2025

510(k) Number: K243691

Submitter's Name/ Contact Person

Manufacturer
Seigla Medical, Inc.
7688 5th St SE
Buffalo, MN 55313
Establishment #: 3017708755

Contact Person
Chad Kugler
CEO and President
Tel: (763) 615-9058
Email: ckugler@seiglamedical.com

Device Information:

Trade Name: LiquID .051 LP Guide Catheter Extension
Common Name: Catheter
Classification: Class II/ Percutaneous Catheter / DQY / 21 CFR 870.1250

Predicate Device:

The Seigla Medical LiquID .051 LP Guide Catheter Extension is substantially equivalent in intended use, method of operation and technical aspects to the following predicate device:

K220691 - LiquID 061 Guide Catheter Extension, LiquID 071 Guide Catheter Extension

Device Description:

The LiquID .051 LP Guide Catheter Extension device is a guide catheter extension that is substantially equivalent to the currently marketed devices with the distinction of having a smaller intraluminal diameter. Guide catheter extensions (GCE) are designed to facilitate the placement of interventional devices. During common clinical practice, a GCE is advanced over a guidewire from within the interior lumen and beyond the distal tip of a conventional guide catheter. These devices allow physicians to achieve deeper vascular intubation providing enhanced placement and support.

The device is currently available in two models: Liquid 061 and LiquID 071 which are designed to fit within 6F and 7F conventional guide catheters, respectively. The LiquID .051 LP Guide Catheter Extension fits within a 6F conventional guide catheter. The 150cm device has a stainless-steel shaft connected to a 15cm single lumen tube. The 15cm single lumen tube catheter body contains a coil for kink resistance and radiopacity. The single lumen tube catheter body is also silicone coated for lubricity. The device has two proximal positioning marks located at 95cm and 105cm from the distal tip. The device handle is color coded to match the standard guide catheter color code.

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 the Predicate Device:

Characteristic	Predicate Device	Subject Device
	LiquID 061 Guide Catheter Extension, LiquID 071 Guide Catheter Extension	LiquID 051 LP Guide Catheter Extension
510(k)	K220691	K243691
Manufacturer	Seigla Medical, Inc	Seigla Medical, Inc
Product Class	II	II
Product Classification	870.1250	870.1250
Product Code	DQY	DQY
Indications 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	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
Single Use or Reusable	Single Use	Single Use
Method of Sterilization	Ethylene Oxide	Ethylene Oxide
Radiopacity	Yes	Yes
Working Length	150 cm	150 cm
Tip ID	0.061, 0.071	0.051

Performance:

Based upon the intended use, descriptive information, and performance evaluation provided in this premarket notification, the Seigla Medical LiquID 051 LP Guide Catheter Extension device has been shown to be substantially equivalent to the currently marketed Seigla Medical LiquID 061 Guide Catheter Extension and Seigla Medical LiquID 071 Guide Catheter Extension device .

The LiquID 051 LP Guide Catheter Extension device has been verified through the following tests:

- Distal Device ID
- Stent Catheter Delivery

- Contrast Injection
- Distal Device OD
- Distal Tensile
- Kink Resistance
- Trackability

Conclusion:

Results of the design control activities performed on the LiquID 051 LP Guide Catheter Extension did not raise any new questions of safety or effectiveness compared to the predicate device. The LiquID 051 LP Guide Catheter Extension is substantially equivalent to the predicate device.