



June 1, 2023

Accurate Medical Therapeutics
Osnat Harbater
R&D and RA Manager
19 Eli Hurvitz Street
Rehovot, 7608802
Israel

Re: K231293

Trade/Device Name: Drakon™ and Sequire® Microcatheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: May 1, 2023
Received: May 4, 2023

Dear Osnat Harbater:

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,

Eleni

For Whatley -S

Gregory O'Connell

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

Digitally signed by

Eleni Whatley -S

Date: 2023.06.01

20:34:10 -04'00'

Enclosure

Indications for Use

510(k) Number (if known)
K231293

Device Name
Drakon™ and Sequire® microcatheters

Indications for Use (Describe)

The Drakon™ and Sequire® microcatheters are intended for the infusion of contrast media into all peripheral vessels. The Drakon™ and Sequire® microcatheters are also intended for drug infusion in intra-arterial therapy and infusion of embolic materials.

The Drakon™ and the Sequire® microcatheters should not be used in cerebral vessels.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

510(k) Summary
Drakon™ and Sequire® microcatheters
510(k) Number K231293

Date Prepared: May 1st, 2023

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

I. SUBMITTER

Company

Accurate Medical Therapeutics Ltd.
19 Eli Hurvitz St
Rehovot, Israel 7608802
+972-54-3386871

Contact Person

Osnat Harbater
19 Eli Hurvitz St
Rehovot, Israel 7608802
+972-54-4557493
osnat@accurmed.com

II. DEVICE

Trade/Device Name:	Drakon™ and Sequire® microcatheters
Common or Usual Name:	Diagnostic Intravascular Catheter
Classification Name:	Catheter, Intravascular, Diagnostic
Regulation:	21 CFR 870.1200
Regulatory	Class: II
Product Code:	DQO

III. PREDICATE DEVICE

Accurate Medical Therapeutics Ltd. claims substantial equivalence to previous submissions of Drakon™ and Sequire® microcatheters, cleared under K173430, K202797, K203487.

IV. DEVICE DESCRIPTION

The Drakon™ and Sequire® microcatheters are single use microcatheters primarily comprised of a luer lock hub, a strain relief cover and tube, central shaft, and a distal tip with radiopaque markers for visualization. The two models differ only in the design of the distal tip. The Sequire®'s distal end has side holes and two radiopaque markers while the Drakon™'s distal end has no side holes and one radiopaque marker. These markers allow for the fluoroscopic visualization of the distal tip of the microcatheters.

The inner lumen is made of PTFE (polytetrafluoroethylene), which allows for the smooth passage of fluids, embolic agents and devices such as guide wires. The distal section of the shaft in both models is coated in a hydrophilic polymer layer, which ensures high lubricity when wet with saline or blood.

The Drakon™ and Sequire® microcatheters are sterile single lumen devices and are available in varying configurations of length (105 cm, 130 cm, 150 or 155 cm, 180 cm), diameters (1.7 Fr., 1.9 Fr., 2.4 Fr, 2.7 Fr., 2.8Fr, and 3.0 Fr.) and tip shape (straight, SP1, SP2).

V. INDICATIONS FOR USE

The Drakon™ and Sequire® microcatheters are intended for the infusion of contrast media into all peripheral vessels.

The Drakon™ and Sequire® microcatheters are also intended for drug infusion in intra-arterial therapy and infusion of embolic materials.

The Drakon™ and Sequire® microcatheters should not be used in cerebral vessels.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is substantially equivalent to the predicate device with respect to indications for use, principle of operation, fundamental design principles, performance, sterilization. The primary reason for submitting this special 510(k) is the addition of sizes (length of up to 180 cm) and availability of different tip shapes for select models (including a packaging change).

These differences do not impact product performance or modify the intended use but are mainly designed to enable additional microcatheter model options to the user in terms of meeting patient anatomies. Therefore, these differences do not raise any new issues of safety and effectiveness.

In summary, the proposed changes do not raise new questions of safety and effectiveness in comparison to predicate device.

VII. PERFORMANCE DATA

Risk assessment pursuant to ISO 14971 was performed to assess the impact of the changes. The following bench tests were performed to evaluate the design elements and performance characteristics of the modified Drakon™ and Sequire® microcatheters and to demonstrate substantial equivalence to the predicate device. The modified Drakon™ and Sequire® microcatheters met the predetermined acceptance criteria:

- Cytotoxicity (ISO 10993-5:2009)
- Guidewire & Guide Catheter Compatibility; Dimensional and Visual Inspection including Tip Shape Dimension
- Bead Compatibility Bench Test

- Vessel Flow Dynamic Indication (Beads Reflux) Bench Test
- Trackability Bench Test
- Tensile Bench Test
- Torque Transmission
- Air Leakage Bench Test
- Liquid Leakage Bench Test
- Burst Pressure Bench Test
- Power Injection Bench Test
- Acute Particulate Matter Evaluation
- Usability
- Sterilization validation is performed in compliance with ISO 11135-1 for a SAL 10^{-6} .
- Shelf life and packaging testing were performed to support the labeled shelf life.

VIII. CONCLUSIONS

The modified Drakon™ and Sequire® microcatheters are substantially equivalent in intended use and indications for use, principles of operation, fundamental design, performance, sterilization, and packaging to the predicate device. Differences between the devices do not raise any new issues of safety or effectiveness. In conclusion, the modified Drakon™ and Sequire® are substantially equivalent to its predicate devices.