October 23, 2020

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

Re: K202797
Trade/Device Name: Drakon™ and Sequre® Microcatheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: September 17, 2020
Received: September 23, 2020

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,

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

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)*
K202797

Device Name
Drakon™ and Sequre® microcatheters

Indications for Use *(Describe)*

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

accuratemedical
a Guerbet company

510(k) Summary
Drakon™ and Sequre® microcatheters
510(k) Number K202797

Date Prepared: October 19th, 2020

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
+972-54-3386871
osnat@accurmed.com

II. DEVICE

Name of Device:	Drakon™ and Sequre® microcatheters
Common or Usual Name:	Drakon™ and Sequre® microcatheters
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 the Sequre NF and Sequre® microcatheters, cleared under K173430

IV. DEVICE DESCRIPTION

The Drakon™ and Sequre® 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 Sequre®'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 Sequre® microcatheters are sterile single lumen devices and are available in several different diameters (1.7 Fr., 1.9 Fr., 2.4 Fr, 2.7 Fr., 2.8Fr, and 3.0 Fr.) and lengths (105 cm, 130 cm, or 150 or 155 cm).

V. INDICATIONS FOR USE

The Drakon™ and Sequre® microcatheters are intended for the infusion of contrast media into all peripheral vessels.
The Drakon™ and Sequre® microcatheters are also intended for drug infusion in intra-arterial therapy and infusion of embolic materials.
The Drakon™ and Sequre® 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, and packaging. The primary reason for submitting this special 510(k) is the addition of sizes that differ in outer and inner diameter and material changes. Note that the 1.7 Fr, 1.9 Fr, and 3.0 Fr. microcatheters also have a minimal addition to the length (from 150 cm to 155 cm).

These differences do not impact product performance or modify the intended use but are mainly designed to reach smaller or larger target vessels in the same anatomy. The Microcatheter's instructions for use identically indicate the sizes requirements for devices compatible with the Microcatheter outer diameter/inner diameter. Therefore, these differences do not raise any new issues of safety and effectiveness.

Although different materials were used in the additional sized models, the materials are all of the same type (e.g. polymer based hydrophilic coating, PTFE, etc). Thus, these changes also 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 change. The following bench tests were performed to evaluate the design elements and performance characteristics of the modified Drakon™ and Sequre® microcatheters and to demonstrate substantial equivalence to the predicate device. The modified Drakon™ and Sequre® microcatheters met the predetermined acceptance criteria.

accuratemedical
a Guerbet company

Biocompatibility testing

The biocompatibility evaluation for the modified Drakon™ and Sequre® microcatheters was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and ISO 10993-1, "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process

The following testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- ISO Intracutaneous Study (ISO 10993-10:2010)
- ISO Guinea Pig Maximization Sensitization Test (ISO 10993-10:2010)
- ISO Acute Systemic Toxicity Study in Mice (ISO 10993-11:2017)
- ASTM Hemolysis Study (ASTM F756 and ISO 10993-12:2012)
- ASTM Partial Thromboplastin Time (ASTM F2382:2018)
- SC5b-9 Complement Activation Assay (ISO 10993-4:2017)
- USP Rabbit Pyrogen Study, Material Mediated (USP General Chapter <151> Pyrogen Test: 2019 and ISO 10993-11: 2017).
- In Vivo Thromboresistance Study in Dogs - Jugular Vein ISO 10993-4:2009

Sterilization, Packaging and Shelf Life Testing

Sterilization validation testing of the Drakon™ and Sequre® microcatheters is performed in compliance with ISO 11135-1 for a SAL 10^{-6}. In addition, shelf life and packaging testing were performed to support the labeled shelf life.

Bench Testing

The following Bench testing was completed successfully by meeting the predefined acceptance criteria:

- Bead Compatibility Bench Test
- Vessel Flow Dynamic Indication (Beads Reflux) Bench Test
- Tensile Bench Test
- Burst Pressure Bench Test
- Torque Strength Bench Test
- Strain Relief Bench Test
- Guidewire & Guide Catheter Compatibility; Dimensional and Visual Inspection
- Bend Radius Bench Test

- Power Injection Bench Test
- Preconditioning and Injected Substances Compatibility Bench Test
- Torque Transmission Bench Test
- Acute Particulate Matter Evaluation
- Air Leakage Bench Test
- Liquid Leakage Bench Test
- Trackability Bench Test

VIII. CONCLUSIONS

The modified Drakon™ and Sequre® 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 Sequre® are substantially equivalent to its predicate devices.