January 26, 2018

Accurate Medical Therapeutics Ltd.
% Ms. Orly Maor
Company Consultant
25A Sirkin Street
Kfar Saba, Israel, 4442156

Re: K173430
Trade/Device Name: SeQure® NF and SeQure® Microcatheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: January 7, 2018
Received: January 10, 2018

Dear Ms. Maor:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173430

Device Name
SeQure® NF and SeQure® microcatheters

Indications for Use *(Describe)*
The SeQure® NF and SeQure® microcatheters are intended for the infusion of contrast media into all peripheral vessels.
The SeQure® NF and SeQure® microcatheters are also intended for drug infusion in intra-arterial therapy and infusion of embolic materials.
The SeQure® NF 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.

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Traditional Premarket Notification Submission – 510(k)

SeQure® NF and SeQure® microcatheters

510(k) Number K173430

Date Prepared: October 30, 2017

I. SUBMITTER

Accurate Medical Therapeutics Ltd.
21 Habarzel Street
Tel-Aviv 6971029 Israel
Tel: +972-54-3386871

Contact Person

Orly Maor
25A Sirkin Street
Kfar Saba 44421, Israel
Tel: +972-9-7453607
Fax: +972-153-9-7453607
oram.ma@gmail.com

II. DEVICE

Name of Device: SeQure® NF and SeQure® microcatheters
Common or Usual Name: SeQure® NF and SeQure® microcatheters
Classification Name: Catheter, Intravascular, Diagnostic (21 CFR 870.1200)
Regulatory Class: II
Product Code: DQO

III. PREDICATE DEVICE

Accurate Medical Therapeutics Ltd. believes that the SeQure® NF and the SeQure® microcatheters are substantially equivalent to the following predicate device:

- Terumo Medical Corporation PROGREAT cleared under K033583 (product code DQO Regulation No. 870.1200)

IV. DEVICE DESCRIPTION

The SeQure® NF 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 SeQure® NF'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 SeQure® NF and the SeQure® microcatheters are sterile single lumen devices and are available in several different diameters and lengths.

V. INDICATIONS FOR USE

The SeQure® NF and SeQure® microcatheters are intended for the infusion of contrast media into all peripheral vessels.
The SeQure® NF and SeQure® microcatheters are also intended for drug infusion in intra-arterial therapy and infusion of embolic materials.
The SeQure® NF and the SeQure® microcatheters should not be used in cerebral vessels.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SeQure® NF and the SeQure® microcatheters have the same intended use as the predicate device. Their indications for use are similar to that of the Progreat predicate device. The dimensions of the SeQure® NF and the SeQure® microcatheters, are comparable to the predicate's. Similar tests and tests methods performed in accordance with the same standards were used in both SeQure® NF and the SeQure® microcatheters and the predicate device to validate the design. The testing results showed that the minor differences in device characteristics between the subject devices and predicate devices do not raise any new questions of safety or effectiveness.
The SeQure® NF and the SeQure® microcatheters have the same technological characteristics as the predicate device as demonstrated in the SE table below:

	SeQure® NF / SeQure® Microcatheter	Progreat	SE JUSTIFICATION
510(k) Number	TBD	K033913	___
Manufacturer	Accurate Medical Therapeutics Ltd.	Terumo Medical Corporation	___
Product Code	DQO	DQO	**Same**
CFR	870.1200	870.1200	**Same**
Intended Use	The SeQure® NF and SeQure® microcatheters are intended for the infusion of contrast media into all peripheral vessels. The SeQure® NF and the SeQure® microcatheters are also intended for drug infusion in intra-arterial therapy and infusion of embolic materials. The SeQure® NF and the SeQure® microcatheters should not be used in cerebral vessels.	The Progreat is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, visceral vessels, and all coronary vessels. The Progreat is also intended for drug infusion in intra-arterial therapy and infusion of embolic materials for hemostasis in procedures including but not limited to Uterine Fibroid Embolization. The Progreat should not be used in cerebral vessels.	**Substantially Equivalent** The SeQure® NF/ SeQure® microcatheter indications for use is within the Progreat indications for use

	SeQure® NF / SeQure® Microcatheter	Progreat	SE JUSTIFICATION
Outer Diameter Proximal/Distal	2.9/2.4 Fr 2.9/2.7 Fr 3.0/2.8 Fr	2.9/2.4 Fr 2.9/2.7 Fr 3.0/2.8 Fr	**Same**
Inner Diameter	0.022” 0.025" 0.027"	0.022” 0.025" 0.027"	**Same**
Guide Catheter Compatibility	Min. 0.038” (0.97 mm) guidewire compatible	Min. 0.038” (0.97 mm) guidewire compatible	**Same**
Working Length	105-150	100-150	**Substantially Equivalent,** included in the same range
Guide Wire Compatibility	0.018" (for 2.4 Fr models) 0.021" (for 2.7/ 2.8 models)	0.018" (for 2.4 Fr model) 0.021" (for 2.7/ 2.8 models)	**Same for each size**
Inner Lumen Material	PTFE	PTFE	**Same**
Metal Reinforcement	Tungsten Braid	Tungsten Coil	**Substantially Equivalent (same material)**
Outer Shaft Material	Multi-polymer tubing	Multilayer polymer tubing	**Same**
Radiopaque Markers	1 or 2 marker bands	1 or 2 marker bands	**Same**
Strain Relief	Yes (polymeric)	Yes (polymeric)	**Same**
Hub connector	Female Luer connector	Female Luer connector	**Same**
Delivery to Site	Over the wire	Over the wire	**Same**
Coating	Hydrophilic coating on the distal section of the outer shaft	Hydrophilic coating on the distal section of the outer shaft	**Same**
Maximum Pressure	2.4 Fr, 2.7 Fr ,2.8 Fr – 900 PSI	2.4 Fr, 2.7 Fr – 750 PSI 2.8 Fr – 900 PSI	**Substantially Equivalent**
Anatomical Site used	Peripheral	Peripheral, coronary	**Substantially Equivalent**
Packaging	Hoop and pouch	Hoop and pouch	**Same**
Environments of Use	Hospitals	Hospitals	**Same**
Sterilization	Sterile for single use (EtO)	Sterile for single use (EtO)	**Same**
Prescription Use	The catheter should be used by a physician who is familiar to the intended procedures.	The catheter should be used by a physician who is familiar to the intended procedures.	**Same**

Based on the above analysis, Accurate Medical Therapeutics Ltd. believes that the SeQure® NF and the SeQure® microcatheters are substantially equivalent to the legally marketed predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Risk analysis** per ISO 14971:2012
- **Biocompatibility testing**

  An evaluation of biocompatibility was performed in compliance with ISO 10993-1. Biocompatibility evaluation included:

#	Test	Standard
1	Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5: 2009
2	Irritation - ISO Intracutaneous Study – Extract	ISO 10993-10:2010
3	ISO Systemic Toxicity Study – Extract	ISO 10993-11: 2010
4	SC5b-9 Complement Activation Assay	ISO 10993-4:2009
5	ASTM Hemolysis	ISO 10993-4:2009
6	Pyrogen Study - Material Mediated	ISO 10993-11:2010
7	ASTM Partial Thromboplastin Time	ISO 10993-4:2009
8	In-Vivo Thrombogenicity, Canine Jugular NAVI (ISO)	ISO 10993-4:2009
9	ISO Maximization Sensitization Test	ISO 10993-10: 2010

  All tests were completed with passing results.

- **Sterilization, Packaging and Shelf Life Testing**

  Sterilization validation testing of the SeQure® NF and the SeQure® microcatheters was performed to demonstrate compliance with ISO 11135-1. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

- **Bench Testing**

  Bench testing included the following:

Tests	
• Bead Compatibility Bench Test	• Power Injection Bench Test
• Vessel Flow Dynamic Indication (Beads Reflux) Bench Test	• Tensile Bench Test
• Embolization Coil Compatibility Bench Test	• Torque Strength Bench Test
• Strain Relief Bench Test	• Guidewire & Guide Catheter Compatibility; Dimensional and Visual Inspection Bench Test
• Bend Radius Bench Test	• Corrosion Bench Test

Tests	
• Torque Transmission Bench Test	• Preconditioning and Injected Substances Compatibility Bench Test
• Air Leakage Bench Test	• Usability Bench Test
• Liquid Leakage Bench Test	• Acute Particulate Matter Evaluation
• Burst Pressure Bench Test	• Trackability Bench Test

All tests met the predefined acceptance criteria.

- **GLP Animal Study**

  GLP Animal Study was performed at the Asaf Harophe GLP facility in Israel by different users in comparison to the predicate device.
  The purpose of the study was to assess the safety and usability of the SeQure® microcatheters.
  No adverse events occurred, devices performed well without malfunction to users' satisfaction. Users were able to perform the required tasks. Gross pathology and histopathology evaluation was also conducted. The test met the predefined acceptance criteria.

VIII. CONCLUSIONS

The SeQure® NF and the SeQure® microcatheters have the same intended use as the predicate device. The principal features of the device that were described, as well as the testing provided, show that the minor differences in device characteristics between the subject device and predicate devices do not raise any new questions of safety or effectiveness.
Performance data and GLP animal study have been provided, establishing that the SeQure® NF and the SeQure® microcatheters perform as intended and in a manner that is substantially equivalent to the predicate.
Therefore, the devices may be found substantially equivalent.