March 21, 2018

Gardia Medical Ltd.
Vardit Segal, Ph.D.
VP Clinical and Regulatory Affairs
2 Ha-Eshel St. P.O. Box 3081
Caesarea Industrial Park 38900, Israel

Re: K180023
  Trade/Device Name: Wirion
  Regulation Number: 21 CFR 870.1250
  Regulation Name: Percutaneous Catheter
  Regulatory Class: Class II
  Product Code: NTE
  Dated: December 27, 2017
  Received: January 3, 2018

Dear Dr. Segal:

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
Indications for Use

WIRION™ is indicated for use as an embolic protection system (EPS) to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting in the carotid arteries and atherectomy in calcified lesions of the lower extremities (LE) arteries. The diameter of the vessel at the site of filter basket placement should be between 3.5mm to 6.0mm. WIRION™ may be used with commercially available 0.014" guide wires.

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.*

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TRADITIONAL 510(K) SUMMARY
WIRION™ Embolic Protection System

Date of summary: March 13, 2018

510(k) Number: K180023

Applicant’s Name: Gardia Medical Ltd.
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Trade Name: WIRION™
Common name: Embolic Protection Device

Classification:
Name: Embolic Protection System
Description: Cardiovascular Percutaneous catheter
Product Code: NTE
Regulation Number: 870.1250
Class: II
Classification Panel: Cardiovascular Percutaneous catheter

Predicate Devices:
Substantial equivalence to the following predicates is claimed:
1. Primary Predicate: SpiderFX Ev3, cleared under 510(k) number K111010.
2. Reference Device: WIRION™ Embolic Protection System;
   Gardia Medical, cleared under 510(k) number K143570.

Device Description:
WIRION™ is an embolic protection system comprised of an independent Filter Unit that can be
delivered, locked and deployed on commercially marketed guide wires, according to physician
preference, anywhere on the wire. The WIRION™ is a rapid exchange system for single use by
a single operator. The WIRION™ is identical to the FDA cleared (K143570) WIRION device
indicated for use in carotid artery stenting (CAS) procedures.
Indication for Use Statement:

WIRION™ is indicated for use as an embolic protection system (EPS) to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting in the carotid arteries and atherectomy in calcified lesions of the lower extremities (LE) arteries.

The diameter of the vessel at the site of filter basket placement should be between 3.5mm to 6.0mm. WIRION™ may be used with commercially available 0.014" guide wires.

Technological characteristics and Substantial Equivalence:

A comparison between the WIRION™ Embolic Protection System and its predicates (the SpiderFX cleared under K111010 and the WIRION cleared under K143570) addressed the device's intended use, system components, functional characteristics, principle of operation, technological characteristics, sterilization, materials and biocompatibility. Based on that comparison it was concluded that the WIRION™ Embolic Protection Device is substantially equivalent to the predicate devices.

Performance Testing:

Clinical and non-clinical tests were conducted. The animal studies conducted on the cleared WIRION are applicable for the expanded indication WIRION. The following additional bench tests were conducted for the expanded indication in order to determine substantial equivalency. All tests met their predetermined acceptance criteria for its intended use.

Non-clinical Data:

The following tests have been performed:

- Embolic capture efficiency and retrieval ability
- Stent Compatibility
- Simulated use

Clinical Data

Clinical data from two clinical studies were utilized to support substantial equivalency of the cleared WIRION EPS (K143570). For the purpose of the expanded WIRION substantial equivalency, a clinical study titled WISE LE: Evaluation of WIRION EPS in Lower extremities arteries was performed. The study aim was to assess safety and performance of the WIRION specific to the expanded indication i.e., the safety and performance of the system in calcified lesions of the lower extremities arteries together with the atherectomy procedure.

WISE LE clinical study:

One hundred and three (103) patients were enrolled in the study. Mean age was 68.2±9.1 and 68.9% of the patients were males. Patients are similar in baseline characteristics to the historical control population.

Primary study endpoint was freedom from major adverse events (MAE) to 30 days post procedure. MAE defined as a serious adverse event that results in death, acute myocardial infarction, thrombosis, pseudo-aneurysm, dissection (grade C or greater) or clinical perforation.
at the filter location, distal embolism (clinically relevant), unplanned amputation, or clinically-driven target vessel revascularization (TVR), through 30 days post-procedure, as adjudicated by the Clinical Events Committee (CEC).

Only two patients had MAE, as adjudicated by the independent Clinical Events Committee (CEC). As indicated in the protocol, the historic controls average MAE rate was 10.6%. From the results it is shown that the WIRION system met the primary endpoint since only 2 patients had MAE which means that MAE rate was 1.9%.

The study analysis compared the proportion of subjects experiencing MAE to the performance goal (PG). The P-value obtained (<0.0001) is significantly lower than one sided alpha = 0.0068 based on the Lan-DeMets alpha spending function with O’Brien - Fleming boundaries thus the study primary endpoint was met.

The WISE LE study demonstrated substantial equivalence of the WIRION EPS to the predicate devices.

The secondary endpoints were device, clinical and technical success.

Device success was defined as successful delivery and deployment of WIRION™ distal to the intervention site without complications, and successful retrieval of WIRION™ following completion of the stenting procedure, without complications. Device success was achieved in 98 of the 103 patients i.e. 95.1% for the ITT population and 94.6% for the PP population.

Clinical success was defined as device success with freedom from procedure related serious adverse events ascribed to the WIRION™. When considering the clinical success for cases in which the WIRION™ was used and no procedure/device related serious adverse events ascribed to the WIRION™ occurred, the clinical success rate is 94.2%. In 97 out of the 103 patients the WIRION™ was successfully used and a good clinical outcome was achieved.

Technical success was defined as freedom from device malfunctioning causing the procedure to be aborted. Technical failure occurred in 3 cases thus the technical success rate was 97.1% for the ITT population and 96.7% for the PP population.

The results are equivalent to the safety and performance data reported in the published literature for the SpiderFX, the legally marketed primary predicate embolic protection device for use in calcified lesions in the lower extremities arteries.

Conclusions:

In light of the above, and all data received from non-clinical and clinical studies, we believe that the WIRION™ Embolic Protection System is substantially equivalent to the SpiderFX (K111010) and WIRION™ Embolic Protection System (K143570).