February 17, 2022

Xcardia Innovation Ltd.
% Orly Maor
Regulatory Consultant
25 Sirkin Street
Kfar Saba, 4442156
Israel

Re: K211679
Trade/Device Name: Xtractor device
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: January 17, 2022
Received: January 21, 2022

Dear Orly 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. 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,

for

Hetal Odobasic
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

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)*

K211679

Device Name
Xtractor™ device

Indications for Use *(Describe)*

The Xtractor™ device is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters, and foreign objects.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional Premarket Notification Submission – 510(k)
Xtractor™ device
510(k) Number K211679

Date Prepared: February 15, 2022

I. SUBMITTER

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II. DEVICE

Name of Device: Xtractor™ device
Common or Usual Name: Xtractor™ device
Classification Name: 21 CFR 870.1310; Vessel dilator for percutaneous catheterization
Regulatory Class: II
Product Code: DRE.

III. PREDICATE DEVICE

Xcardia Innovation Ltd. believes that the Xtractor™ device is substantially equivalent to the following predicate device:

- Spectranetics TightRail™ Mechanical Dilator Sheath Set cleared under K140047 (product code DRE Regulation No. 21 CFR 870.1310) and in subsequent submission under K142546 TightRail and TightRail Mini Rotating Dilator Sheaths.

IV. DEVICE DESCRIPTION

The Xtractor™ device is a single use sterilized device designed to be advanced through the veins over a cardiac pacemaker/defibrillator lead.

The device is a motor driven mechanical tool that is introduced over the lead and follows its path, using a flexible and steerable shaft connected to a control handle.

The proximal section of the shaft maintains pushability while the distal section is very flexible, to facilitate easy passage through vein curves and junctions. The device' distal tip is designed to facilitate dilation of fibrous binding tissue and passage through calcified binding sites along the implanted lead (for example by use of combined rotational and impact movements).

The device' control handle, which is connected to the shaft, contains a steering mechanism for assisting the device maneuverability, and a motorized power transmission mechanism to activate the device tip.

The Xtractor™ device is visible under fluoroscopy during the procedure.

V. INDICATIONS FOR USE

The Xtractor™ device is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters, and foreign objects.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Xtractor™ device has the same intended use as the predicate device. Its indications for use are identical to that of the predicate device.

The Xtractor™ device has similar technological characteristics as the predicate device as demonstrated in the table below:

	Xtractor™	**TightRail™**	**SE JUSTIFICATION**
510(k) Number	K211679	K140047	___
Manufacturer	Xcardia Innovation Ltd.	Spectranetics, Inc.	___
Product Code	DRE	DRE	**Same**
CFR	21 CFR 870.1310	21 CFR 870.1310	**Same**
Intended Use	The Xtractor™ device is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters, and foreign objects.	The TightRail™ Rotating Dilator Sheaths are intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters, and foreign objects.	**Same**
Nominal Outer Diameter	7.75mm	6.6mm without sheath and is designed to be used with a 8.1mm sheath	**Similar** The nominal outer diameter is similar.

	Xtractor™	**TightRail™**	**SE JUSTIFICATION**
Nominal Inner Diameter	13Fr	9,11,13 Fr	**Similar** The nominal inner diameter is similar.
Nominal effective length	540mm	475mm	**Similar** The nominal effective length is similar.
Radiopacity Markers	Device: Radio-detectable materials source is the dense layers of stainless steel coils Sheath: Radio-detectable materials source is Teflon compounded with 10-12% bismuth	Device: Radio-detectable materials source is the dense layers of stainless steel coils Sheath: Radio-detectable materials source is Teflon compounded with bismuth trioxide	**Similar** The radiopacity markers are similar.
Blade design	Two circular rings: a rotating blade for dilation, and a blunt impact ring for axial dilatation	Serrated / Interrupted Beveled Edge Blade includes an axial translation during rotation.	**Similar** Both designs are suitable for dilation of surrounding tissue.
Blade feature	Shielded Blade is covered by the blunt ring.	Shielded Blade is retracted into the shaft.	**Similar.** Achieved by different but substantially equivalent mechanism.
Materials	Stainless Steel, Pebax Jacket PTFE Teflon with bismuth for radiopacity Hydrophilic coating	Stainless Steel, Pebax Jacket PTFE Teflon with bismuth trioxide for radiopacity	**Similar**
Shaft Design	Shaft is designed to provide a flexible means of aligning the shaft and tip assembly parallel to the vessel wall in the expected curvature of the anatomy.	Shaft is designed to provide a flexible means of aligning the shaft and tip assembly parallel to the vessel wall in the expected curvature of the anatomy.	**Same**

	Xtractor™	**TightRail™**	**SE JUSTIFICATION**
Outer Sheath / External Sheath design	Outer Sheath / Teflon (radio-detectable) Beveled distal end (to navigate the expected curvature of the anatomy) The Xtractor™ external sheath has flare proximal end for convenient grip. The Xtractor™ device (not the sheath) already has a blunt proximal end, thus supports counter traction to release of the lead from the myocardium	Outer Sheath / Teflon (radio-detectable) Beveled distal (to navigate the expected curvature of the anatomy) Blunt straight proximal end when flipped around (to provide a blunt surface for counter-traction at the release of the lead from the myocardium)	Both devices have same purpose and similar performance for supporting the procedure and entry into the vessel.
Anatomical Site used	From pacemaker pocket, through the veins, along the path towards the heart	From pacemaker pocket, through the veins, along the path towards the heart	**Same**
Environments of Use	Physicians knowledge in the techniques and devices for lead or catheter removal	Physicians knowledge in the techniques and devices for lead or catheter removal	**Same**
Sterilization	Sterile for single use (EtO)	Sterile for single use (EtO)	**Same**
Device Life	Disposable	Disposable	**Same**
Prescription Use	The device should be used by a physician who is familiar with the intended procedures.	The device should be used by a physician who is familiar with the intended procedures.	**Same**
Operation	Battery operated	Mechanical	Testing demonstrated substantial equivalence with respect to safe operation
Haptic feel	The user advances the device and pulls the lead manually. The user activates the motorized rotation of the shaft using the handle's button or pedal.	The user advances the device and pulls the lead manually. The user rotates the shaft by manual squeezing of the trigger on the handle.	The user advances the device and pulls the lead in exact same way. Rotation is achieved by different but substantially equivalent mechanisms.

	Xtractor™	**TightRail™**	**SE JUSTIFICATION**
Mechanisms of action/tissue interaction	The Xtractor™ has a rotating dilation blade that rotates to assists the user in separating the tissue that is bound around the lead. The blade has sharp teeth that when pushed against the fibrotic tissue are used to assist in separating it. The Xtractor™ has a "combined" mode	The TightRail™ device has a rotating dilation blade that rotates to assist the user in separating the tissue that is bound around the lead. The blade has sharp teeth that when pushed against the fibrotic tissue are used to assist in separating it. The TightRail™ device is actually working in a similar "combined" mode.	The mechanism of action, tissue interaction, and full control by the user is similar for both devices. For the Extractor™, the total amount of rotary dilation is controlled by the duration of button press and in the predicate device by number of squeezes. The Xtractor™ enables the user to select modes in which only sub-set of the actions would be performed. The activation is fully controlled by the user in both devices. The user can start and stop the shaft rotation at any time and change mode as desired in the Xtractor™.
Pedal	The Xtractor has a pedal that includes the battery and electrical circuitry to drive the handle's motor, LED display and buttons. The pedal can be used to select modes and for device activation.	NA	The Xtractor™ pedal provides battery power, mode selection and for convenient use by user. The Xtractor™ can be used to release the hand of the user from manually squeezing the trigger as in the predicate device. The activation is fully controlled by the user in both devices. The user can start and stop the shaft rotation at any time and change mode as desired in Xtractor™. Electrical safety, EMC and software testing were provided for the Xtractor.

VII. PERFORMANCE DATA

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

- **Biocompatibility**
  Biocompatibility evaluation in compliance with ISO 10993-1 was performed.
  The following tests were conducted:
  Cytotoxicity Study Xtractor™ -Device
  Cytotoxicity Study- Handle
  Cytotoxicity- pooling rod
  ISO Intracutaneous /irritation Study
  Sensitization Test
  Acute Systemic toxicity
  SC5b-9 Complement Activation Assay
  ASTM Hemolysis
  Pyrogen Study - Material Mediated
  ASTM Partial Thromboplastin Time with Sponsor Provided Control
  NAVI
  The device was found biocompatible.

- **Sterilization, Packaging and Shelf Life Testing**
  Sterilization validation was performed to demonstrate compliance with ISO 11135-1. In addition, transportation simulation and environmental tests prior shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

- **Performance Testing**
  Performance testing included the following:

Name of test	Test description
Bending Test	The test was done to verify that the Xtractor™ device is functional after working in an extreme bending radius.
Corrosion Resistance	Corrosion resistance was tested per ASTM A967/A967M
Device radiopacity	The test was done to verify that the Xtractor™ device is visible under fluoroscopy.
Dimensional Verification	Measurements following sterilization of the Xtractor™ device critical dimensions were taken.
Tensile strength	The test was done to define the tensile strength of the Xtractor™ device and the External Sheath.
Extended use	Test was done to verify that the Xtractor™ device is not damaged by the procedure and remains without

Name of test	Test description
	signs of defects, wear or deformations in substantially extended and/or extreme use
Torque test	Torque transmission from the handle to the distal tip both inner and outer shaft was tested.
Simulated use	Simulated use of the device in anatomical model simulator was done in time T0 and time Tx (shelf life)
Hydrophilic coating testing	3 tests (particles, visual, and pinch test) that demonstrated that the device coating performs as intended.
Xtractor™ vs. Predicate comparison test	Performance was done between the devices for dilating performance and Lead pull force.

All tests passed and met the predefined acceptance criteria.

- **Software Validation**
  The Xtractor™ device level of concern is moderate. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

- **Electrical Safety and EMC**
  Electrical Safety per IEC 60601-1 and Electromagnetic compatibility (EMC) per IEC 60601-1-2 were conducted on the Xtractor™ Lead Extraction device.

VIII. CONCLUSION

The Xtractor™ device was determined to be substantially equivalent to the predicate devices.