September 29, 2023

Advanced Surgical Concepts
Edward Hyland
Director of Quality & Regulatory
Unit 4, Sunnybank Center
Upper Dargle Road
Bray, WK A98 E339
Ireland

Re: K232701
Trade/Device Name: Guardenia (GAR-1)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 30, 2023
Received: September 5, 2023

Dear Edward Hyland:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.09.29 14:29:15 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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.

Submission Number *(if known)*

Device Name

Guardenia (GAR-1)

Indications for Use *(Describe)*

The Guardenia contained extraction system is indicated to contain and isolate tissue during, or prior to, surgical removal and /or extracorporeal manual morcellation.

Contraindications:

Guardeniais contraindicated for use with laparoscopic power morcellators.

Guardenia is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

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.

510(k) Summary

Prepared on: 2023-09-25

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Advanced Surgical Concepts
Applicant Address	Unit 4 Sunnybank Center, Upper Dargle Road Bray WK A98 E339 Ireland
Applicant Contact Telephone	+35312864777
Applicant Contact	Mr. Edward Hyland
Applicant Contact Email	Ed@advancedsurgical.ie

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Guardenia (GAR-1)
Common Name	Tissue Bag
Classification Name	Accessory to endoscope
Regulation Number	21 CFR 876.1500
Product Code	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211234	RedEx	GCJ
K211043	Alexis CES	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

Device Description Summary
The Advanced Surgical Concepts Ltd, Guardenia, is a contained extraction system; proposed under classification regulation 21 CFR 876.1500, device class II and product code GCJ.

The device is provided sterile for single use.

Guardenia consists of a flexible specimen containment/extraction Bag, with an integrated Opening Ring and Bag Tether with a separate Guard component to protect the Bag and incision during morcellation with a scalpel.

The Bag is made from polyurethane (PU) film and comes preloaded in an Introducer. There is a Plunger to deploy the Bag into the abdominal cavity. Any standard sized 12mm trocar cleared to market by the FDA may be used as an accessory for device deployment. A blue arrow on the Introducer provides the user with an indicator of the correct orientation during deployment in the abdominal cavity to ensure the Bag is correctly deployed.

After the Bag is ejected from the Introducer into the abdominal cavity, the nitinol wire Opening Ring recovers its shape, opening the mouth of the Bag. This facilitates the encapsulation of the specimen. When the specimen is encapsulated, the Bag Tether, which extends externally through the trocar after deployment, is pulled, pulling the Opening Ring out through the trocar. This action also closes the mouth of the Bag inside the abdomen.

The incision is then increased to the required size (2.5-6 cm) prior to removal of the trocar. The trocar is removed, the mouth of the Bag is

exteriorized, and then opened outside the abdomen. If the specimen is small enough, the Bag and specimen can be removed at this stage without the need for morcellation or the use of the Guard.

If the specimen requires reduction, the Guard must be deployed first.

To deploy the Guard, the free end of the Guard (the end opposite to the blue Guard Ring) is inserted through the mouth of the Bag. The yellow Anchor Ring is then inserted through the center of the deployed Guard. The Guard is actuated by flipping the Rolling Ring inward, until the incision is maximized. The Guard Petals, which are made from a tough polyethylene (PE) film, overlap, and conform to the incision, protecting the incision & Bag from damage due to inadvertent scalpel strikes or the traumatic graspers that are used to grasp and hold the tissue specimen at the incision.
The physician then performs extracorporeal manual morcellation using a grasper and a scalpel. When the tissue specimen has been removed or sufficiently reduced, the surgeon flips the Rolling Ring in the opposite direction two or three times and pulls on the Removal Ribbon to remove the Guard. The Bag is removed by grasping the Opening Ring and carefully removing the Bag from the incision.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Guardenia contained extraction system is indicated to contain and isolate tissue during, or prior to, surgical removal and /or extracorporeal manual morcellation.

Contraindications:

Guardeniais contraindicated for use with laparoscopic power morcellators.

Guardenia is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Guardenia device and its predicate the Redex device have the same indications for use and intended use. The change and subject of the special 510k notice is to remove a contraindication, "Do not use on tissue that is known or suspected to contain malignancy." The proposed change to the contraindications, precautions, and Use sections of the IFU is in keeping with the indications for use and intended use of the device. The contraindication was inappropriate in that it prevented the device from being used as an containment/ extraction bag for malignant tissue even when in the physician's judgment, the use of the device would be in the patient's best interest. A precaution was added to ensure the physician is informed of the risk of occult uterine cancer. "Use caution when using the Guardenia contained extraction system for removal/manual morcellation of uterine tissue. Uterine tissue may contain unsuspected cancer." The language for the precaution is taken directly from the reference device the Applied Medical Alexis CES device K211043. Furthermore, the reference device has no contraindication for malignant tissue.

Technological Comparison

21 CFR 807.92(a)(6)

There is no change to the physical device between the Gardenia and its predicate the RedEx device. Therefore the technological characteristics and principles of operation are identical. Thus, Guardenia is substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

This Special 510(k) is for a label change only. There is no non-clinical or clinical tests required to support the change.