May 28, 2020

LifeCell Corporation
Bozhana Hegarty
Manager, Regulatory Affairs
One Millennium Way
Branchburg, New Jersey 08876

Re: K193539
Trade/Device Name: REVOLVE ENVI 600 Advanced Adipose System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: April 29, 2020
Received: April 30, 2020

Dear Bozhana Hegarty:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193539

Device Name
REVOLVE ENVI™ 600 Advanced Adipose System

Indications for Use *(Describe)*

REVOLVE ENVI™ 600 System is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

REVOLVE ENVI™ 600 System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

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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1 510(K) SUMMARY

1.1 SUBMITTER

Name and Address of Submitter:

LifeCell Corporation
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Contact:

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Prepared by and Date:

Bozhana Hegarty
April 29, 2020

1.2 SUBJECT DEVICE

Trade name: REVOLVE ENVI™ 600 Advanced Adipose System
Common Name: Suction Lipoplasty System
Classification Name: System, Suction, Lipoplasty (21 C.F.R. §878.5040)
Device Class: Class II
Product Code: MUU

1.3 PREDICATE DEVICE

Predicate Device:

REVOLVE™ Advanced Adipose System (cleared as "GID 700" via K120902)

Reference Device:

REVOLVE ENVI™ 600 Advanced Adipose System (cleared via K163647)

1.4 Device Description

REVOLVE ENVI™ 600 Advanced Adipose System (REVOLVE ENVI 600 System) consists of a sterile, single-use canister and components intended to be used for harvesting, filtering and transferring of autologous adipose tissue. Such products have been classified by FDA as Class II devices under 21 CFR §878.5040, Suction Lipoplasty System, and assigned product code MUU. The subject device should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. The adipose tissue is harvested from the patient using liposuction tubing and cannula that are supplied by the user or the institution. The harvested tissue is collected inside the device which contains an inner basket with 200 µm mesh filter that can process up to 600 mL of collected tissue. A manual stirring assembly allows the user to mix the tissue and Lactated Ringer's during the washing step. The processed adipose tissue is removed from the device via an extraction port located on the bottom of the device using a syringe.

The REVOLVE ENVI 600 System is comprised of the following components, intended to be used only as a system:

- Canister (including mesh filter)
- Syringe Adapter
- Temperature Strip
- Lactated Ringer's Tubing Set
- Vacuum Tubing Set

The device is offered in a single size, is packaged in a thermoformed tray and Tyvek® lidding and is sterilized via gamma irradiation. The device is a single-use device to be used in a healthcare facility.

1.5 Indications for Use

REVOLVE ENVI™ 600 System is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

REVOLVE ENVI™ 600 System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

1.6 TECHNOLOGICAL CHARACTERISTICS

The subject device, REVOLVE ENVI 600 System, and the predicate device, REVOLVE System, are both lipoplasty suction systems used in the aspiration, harvesting, filtering and transferring of autologous adipose tissue. Both devices have the same intended use, principle of operation and consist of a canister, mesh filter, extraction port and components used to collect, filter and transfer the adipose tissue during lipoplasty procedures. A mesh filter is used to capture the collected tissue in both devices. The vacuum source is user or institution supplied. Various ports on the canister of both devices are provided to access the vacuum source (vacuum port), collect the adipose tissue (liposuction port), and receive the Lactated Ringer's solution during washing (Lactated Ringer's port). The subject device has a dedicated port to transfer the filtered tissue (extraction port), whereas the predicate device utilizes the liposuction port for extraction. Additionally, the subject device has a larger processing volume, new materials of construction and is sterilized via gamma irradiation, compared to electron beam irradiation for the predicate device.

The subject device, REVOLVE ENVI 600 System, is a modified version of the reference device, cleared with the same trade name under K163647. The differences between the subject and reference devices include design modifications of existing parts, addition of new components, and addition of a new supplier.

1.7 PERFORMANCE

REVOLVE ENVI 600 System has undergone appropriate performance and biocompatibility testing to ensure safety and effectiveness of the device. Stability testing was completed to support the proposed shelf life. The sterilization of the device is assured using a sterilization method validated in accordance with ISO 11137-2:2013 "*Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*" to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Biocompatibility:

In accordance with ISO 10993-1:2018 – "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," REVOLVE ENVI 600 System is classified as Externally Communicating Device, Tissue, Limited Contact (≤ 24 hours). The subject device has undergone appropriate biocompatibility assessments and testing, and data demonstrates that the device is biocompatible.

Bench Testing:

Bench testing was performed to support substantial equivalence to the predicate device. The table below provides a list of performance tests conducted on the subject device to demonstrate substantial equivalence.

Bench Testing/Assessment	Applicable Standard
Gross and microscopic assessments of adipose samples	N/A
Adipose tissue viability (via Lactate Dehydrogenase assessment)	N/A
System fluid leak	N/A
System vacuum leak	N/A
Tubing connection tensile strength	N/A
Hose collapse	ISO 10079-1:2015(E) Medical Suction Equipment Part 1, Section 6.3.1 and Annex A.4
Implosion test	ISO 10079-1:2015(E) Medical Suction Equipment Part 1, Section 6.1.3 and Annex A.3

Substantial equivalence data demonstrate that REVOLVE ENVI 600 System is comparable to the predicate REVOLVE System in product performance characteristics relevant to the intended use of the device.

1.8 CONCLUSION

In summary, REVOLVE ENVI 600 System, subject of this 510(k), is substantially equivalent in its intended use, principle of operation and performance to its legally marketed predicate device, REVOLVE System (K120902).