LifeCell Corporation
Attention: Anuja Yardi
One Millennium Way
Branchburg, NJ 08876

February 9, 2023

Re: BK220709 (Formally K163647)
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: QKL

Dear Ms. Yardi:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 25, 2017. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

For more information, please refer to the Federal Register Notice *Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care To Produce a Therapeutic Article* (86 FR 50887, available at https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Julia Russell at 240-704-0618 or by email at Julia.Russell@fda.hhs.gov.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66 G609
Silver Spring, MD 20993 0002

August 25, 2017

Lifecell Corporation
Ms. Anuja Yardi
Regulatory Affairs Specialist
One Millennium Way
Branchburg, New Jersey 08876

Re: K163647
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: July 25, 2017
Received: July 26, 2017

Dear Ms. Yardi:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K163647

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7. 510(K) SUMMARY

7.1 SUBMITTER

Name and Address of Submitter:
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Contacts:
Anuja Yardi
Senior Regulatory Affairs Analyst
Phone: (908) 947-1018
Fax: (908) 325-0020

Jessica Campagna
Associate Director, Regulatory Affairs
Phone: (908) 809-7852
Fax: (908) 325-0020

Prepared by and Date:
Anuja Yardi
December 22, 2016

7.2 SUBJECT DEVICE

Name of Device: Revolve™ Envi 600 Advanced Adipose System
Common or Usual Name: Suction Lipoplasty System
Classification Name: System, Suction, Lipoplasty (21 C.F.R. §878.5040)
Device Class: Class II
Product Code: MUU

7.3 PREDICATE DEVICE

Predicate Device:
Revolve ™ System (cleared as "GID 700" via K120902)
The predicate device has not been subject to a design-related recall.

7.4 DEVICE DESCRIPTION

Revolve Envi 600 System consists of a sterile, single use canister and accessories 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 is intended to be used with a legally marketed vacuum or aspirator apparatus as a source of suction. The adipose tissue is collected from the patient using liposuction tubing and cannula that are supplied by the user or the institution. This tissue is harvested inside the canister which contains a 600ml inner basket with 200µm mesh filter. A manual stirring assembly allows the user to mix the tissue and fluids 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.

For user convenience, the device is supplied with the following accessories designed for use with the Revolve Envi 600 System:

- Luer extraction tip
- Toomey and catheter syringe extraction tip
- Toomey/Catheter tip syringe to Luer syringe adapter
- Temperature strip
- Lactated Ringer's tubing set
- Suction tubing set.

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

Device Materials

List of Materials for Revolve ENVI 600 System Components		
Name of Component		**Raw Material**
Handle Assembly		Acrylonitrile butadiene styrene (ABS)
Manifold Assembly*		ABS, Thermoplastic Elastomers
Filter*		Polytetrafluroethylene
Canister*		Polycarbonate
Mesh Basket	Lower Cap*	ABS
	Shaft*	
	Comb*	
	Mesh Basket*	Polycarbonate

List of Materials for Revolve ENVI 600 System Components		
Name of Component		**Raw Material**
	Mesh*	Monofilament Nylon 6A
Base	Base	ABS
	Extraction Port*	
	Extraction Port Insert*	
Accessories	Luer Extraction Tip*	ABS
	Toomey/Catheter Extraction Tip*	
	Toomey/Catheter to Luer Adapter*	
	Temperature Strip	LCR Hallcrest P/N 4573 ADP
	Lactated Ringer's tubing set*	Polyvinyl chloride
	Suction tubing set*	

**Tissue Contacting Component*

Device Specifications

Canister Volume	1500 ml
Processing Volume	600 ml
Ports	Vacuum, Lactated Ringer's (LR), vent, patient, extraction
Filter	200µm mesh filter
Source of Energy	User Supplied Vacuum

7.5 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..

7.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject 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 accessories used to collect, filter and transfer the adipose tissue during lipoplasty procedures. When the tissue is collected into the canister, it is filtered through a mesh filter to capture the tissue. The vacuum source is user or institution supplied. Various ports on the canister on both devices are provided to access the vacuum source (vacuum port), collect the adipose tissue (patient port) , receive the Lactated Ringer's solution during washing (Lactated Ringer's port) and transfer the filtered tissue (extraction port).

7.7 PERFORMANCE

The subject device, Revolve Envi 600 System has undergone appropriate performance, biocompatibility and shelf life testing to ensure safety and effectiveness of the device. 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, the subject device, Revolve Envi 600 System is classified as: Externally Communicating Device, Tissue, Limited Contact (≤24 hours). The subject device was tested in accordance with the tests recommended in the FDA's General Program Memorandum #G95-1 – "*Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* and International Standard ISO 10993-1:2009 –"*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* Revolve Envi 600 System has passed cytotoxicity, sensitization, irritation, acute systemic toxicity and material mediated pyrogenicity testing demonstrating 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 both the subject and predicate devices to demonstrate substantial equivalence.

Bench Testing / Evaluation	Applicable Standard
Adipose tissue viability (via Lactate Dehydrogenase assessment)	N/A
Simulated use testing which included the	N/A

Bench Testing / Evaluation	Applicable Standard
evaluation of the following device characteristics: - Device stability - Leakage during extraction and processing - Time from completion of harvest to having processed adipose material ready for injection - Ability to remain functional when subjected to vacuum (29.9 inHg) - Tubing Connection Tensile Strength	

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.

Clinical Testing:
No clinical testing was included in this submission.

7.8 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).