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## 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

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## Device identification

Common Name: Suction Lipoplasty System

Device Name: Lipoaspirate Washing System for Aesthetic Body Contouring

Proprietary Name: Viality™ Lipoaspirate Wash System for Aesthetic Body

Contouring Product Code: QKL

Classification: Class II

## Predicate device

Primary predicate: AuraClens™ Suction Lipoplasty System (A 123 + AuraClens)

Predicate 510(k): BK190433

Reference Predicate: REVOLVE ENVI 600 Advanced Adipose System

Predicate 510(k): BK220721

## Equivalence

The product code, common name, indications, operational principle, sterilization method, shelf life, key technological characteristics, and contraindications are identical to those of

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the predicate device. Slight differences in materials and design are shown to have no impact on the safety and effectiveness of the device.

### **Intended use / indications for use**

The device is indicated for use to filter and wash aspirated, harvested 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 to be used without any additional manipulation.

The indications for use are identical to those of the predicate device and no new indications are proposed.

### **Device description and technological characteristics**

The subject and predicate devices utilize fundamentally the same technology and scientific principles. The processing steps are the same, e.g., a three-step lipoplasty system for 1) harvesting, 2) washing/filtering, 3) concentrating/transferring adipose tissue. They are both intended to be used with a legally marketed vacuum or aspirator apparatus as a means of suction. No new modes of action are introduced.

The subject device has the same technological characteristics (consisting of the following primary components: chamber, concentration tray, basket, auracLens, and spatula), design concept, and process steps as the predicate device.

### **Sterilization and shelf life**

The subject device uses the same sterilization method and sterility assurance level as the predicate device. The labeled shelf life of two (2) years is supported by equivalent packaging configuration and stability evaluation and does not raise new questions of safety or effectiveness.

### **Contraindications**

The contraindications for use are identical to those of the predicate device. No new contraindications are introduced.

### **Performance data**

Performance testing, including bench testing, biocompatibility, shelf life, and transit testing, demonstrate the substantial equivalence of the subject device to the predicate device.

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## **Conclusion**

The Viality™ Lipoaspirate Wash System for Aesthetic Body Contouring (Viality-1400) is substantially equivalent to the predicate device.