510(k) Summary
Prepared: November 13, 2025

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III.	**Product Trade Name**	Puregraft SYNC Adipose Filtration System
IV.	**Common Name**	Lipoaspirate Washing System For Aesthetic Body Contouring
V.	**Regulation Name**	Suction Lipoplasty System
VI.	**Regulation Number**	21 CFR 878.5040
VII.	**Regulatory Class**	Class II
VIII.	**Product Code**	QKL
IX.	**Predicate Device**	K092923/ BK220689, Cytori Puregraft 250/PURE System

X. Description

The Puregraft SYNC Adipose Filtration System is a sterile, single-use, closed system. The system consists of a harvest canister containing a Puregraft filtration bag, which is filled through the lid manifold and inlet/waste tubing sets. The Puregraft SYNC System is used in-line with a vacuum or aspirator apparatus and a suitable liposuction cannula.

XI. Indications for Use

The Puregraft SYNC Adipose Filtration System is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.

XII. Summary of the Technological Characteristics

The Puregraft SYNC Adipose Filtration System is a sterile, single-use, closed system. The system consists of a harvest canister containing a Puregraft filtration bag, which is filled through the lid manifold and inlet/waste tubing sets. The system includes the following accessories which are utilized during harvesting or processing:

- Drain Bag

- Combined Adapter (2)
- Catheter Tip Syringe (2)
- Slider
- MicroAire PAL Adapter
- Mayo Stand Clamp

The Puregraft SYNC System is used in-line with a vacuum or aspirator apparatus and a suitable liposuction cannula. Lipoaspirate is introduced to Puregraft bag by way of the inlet tubing set and canister lid. Waste fluid is automatically drained and patient tissue is retained in the Puregraft bag.

Once the bag is filled to the desired capacity, the pre-drained tissue is washed using Lactated Ringer's solution. The filtered tissue can then be harvested from the Puregraft bag.

The fundamental scientific technology, materials of construction, processing methods, and mechanism of operation are the same between the subject and predicate devices. Both devices are provided sterile, designed to filter and wash adipose tissue using a mesh filter. Both devices contain the same patient-contacting materials. Both devices are single-use and designed to accept a volume of tissue, and then undergo minor manual manipulation to obtain purified adipose tissue for reinjection. The table below summarizes the comparison of technological characteristics between the subject and predicate devices.

The table below illustrates that the subject device, when compared to the predicate device, is the same in all factors that could affect the safety and/or effectiveness of the device. Differences between the two devices are minimal and do not raise new questions of safety or effectiveness. Therefore, this comparison table supports the substantial equivalence of the subject device to the predicate device.

Table 10-1: *Device Comparison Table*

	Predicate Device (Cytori Puregraft 250/PURE System, K092923/ BK220689)	**Subject Device** (Puregraft SYNC Adipose Filtration System)
Product Code and Class	QKL Class II	QKL Class II
Indications for Use	The Puregraft 250 System is indicated for use in the harvesting,	The Puregraft SYNC Adipose Filtration System is indicated for use

	filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.	in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.

Components	• Puregraft 250 Bag
	• Puregraft 250 Drain Bag
	• Combined Adapter (2)
		• Puregraft SYNC System
		  ○ Second-generation Puregraft bag (built-in)
		  ○ Puregraft 250 Drain Bag
		  ○ Harvest canister and lid manifold
		• Accessories Kit
		  ○ Combined Adapter (2)
		  ○ Catheter Tip Syringe (2)
		  ○ Slider
		  ○ MicroAire PAL Adapter
		  ○ Mayo Stand Clamp

Patient-Contacting Materials	• Polycarbonate • Polypropylene • Polysulfone • Silicone • PVC • ABS • Polyester	• Polycarbonate • Polypropylene • Polysulfone • Silicone • PVC • ABS • Polyester
Principle of Operation	The Puregraft 250 System is a sterile, single-use, closed system.	The Puregraft SYNC Adipose Filtration System is a sterile, single-use, closed system
Provided sterile	Yes	Yes
Tissue collection capacity	400 mL	500 mL
Biocompatibility	Meets ISO 10993 requirements for Externally communicating medical device, contact with tissue/bone/dentin, limited (<24 hours) contact duration	Meets ISO 10993 requirements for Externally communicating medical device, contact with tissue/bone/dentin, limited (<24 hours) contact duration
Sterilization	Gamma irradiation	Gamma irradiation

Mechanical testing	See prior 510(k)	Sterile barrier integrity: PASS Product integrity: PASS Device connections, tensile strength: PASS
Bench testing	See prior 510(k)	Biological comparison to predicate: PASS Biological testing of aged and unaged devices: PASS

The indications for use, principles of operation, and function of the Puregraft SYNC Adipose Filtration System have been shown to be substantially equivalent to those of the Puregraft 250 System (K092923/ BK220689).