510(K) SUMMARY
Synova WAVE Adipose Processing System

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Application Number: BK251268

Contact Details

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Device Name:

Device Trade Name: Synova WAVE Adipose Processing System
Common Name: Suction lipoplasty system
Classification Name: Lipoaspirate Washing System For Aesthetic Body Contouring
Regulatory Number: 878.5040
Product Code: QKL

Legally Marketed Predicate Devices

Predicate #: B220703
Predicate Trade Name: Lipogems System
Product Code: QKL

Device Description Summary

The Synova WAVE adipose tissue processing system is intended for the closed-loop processing of lipoaspirate tissue for the transferring of adipose tissue. The system consists of two primary components:

a. Synova WAVE device is an electromechanical device that applies energy to the adipose tissue.

b. Synova WAVE disposable, single-use cartridge is a sterile cartridge designed to house the adipose tissue during processing.

The result of processing with the Synova WAVE adipose tissue processing system is washed adipose tissue, which allows a patient's subcutaneous fat to be processed for autologous reinjection within the operative procedure time.

There is no direct interaction of the device with the patient, although the adipose tissue that is processed in the device comes from the patient and is returned to the same patient after processing.

Intended Use / Indications for Use

The Synova WAVE system is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue for the purpose of transferring autologous adipose tissue for aesthetic body contouring (lipofilling) in applications including plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.

Indications for Use Comparison

The Indications for Use are the same.

Technological Comparison

The subject device and the predicate device share many identical or similar features and parameters including the product code and indication for use. Differences exist in the following areas:

- Variations: Predicate has two size variations; Synova has only one size of 500 mL.
- Source of Energy: Predicate uses manual processing; Synova uses 24 VDC power.
- Mechanical Operation: Predicate is processed by hand; Synova is an automated process driven by an electric motor.
- Agitation Mechanism: Predicate uses stainless steel balls that are manually shaken to mechanically impact and agitate the adipose tissue; Synova is automated and electro-mechanically agitates the adipose tissue.
- Fill Volume: Predicate comes in two sizes that can hold a total of 60 mL or 240 mL; Synova is a single size that can hold a total of 500 mL.
- Number of Ports: Predicate has two open luer ports for input and output access; Synova has two self-sealing needleless injection luer ports and one self-sealing catheter port for input and output access.
- Mesh Sizes: Predicate passes adipose tissue through a 2000 µm filter at its luer inlet and a 1000 µm filter at its luer outlet; Synova passes adipose tissue through 1200 µm ports for input and output.
- Tissue Collection: Predicate collects adipose tissue and residual adipose from the container through repeated shaking and draining of saline; Synova collects adipose tissue and residual adipose directly from the cartridge and by centrifuging saline.

The most significant difference between the subject and predicate is that the predicate uses manual shaking to wash and process adipose tissue whereas the Synova WAVE device uses an automated powered impact plate to wash and process adipose tissue. Other differences were only minor variations in size and access.

None of the differences substantively affect the output of the Synova WAVE compared to the predicate device and so do not raise any new concerns for safety or efficacy.

An adipocyte viability analysis was conducted that compared the subject device to the predicate device. A complete study report is included in this submission.

The totality of performance testing and standards compliance demonstrates that the differences in device design and operation do not raise any new concerns for safety or efficacy, and therefore the subject device and the predicate device are substantially equivalent.

Non-Clinical and / or Clinical Tests Summary and Conclusions

Cell Viability testing was conducted to compare the results to the predicate device.