510(k) Summary - BK251197

1. **Type of Submission:** Traditional

2. **Date of Summary:** December 22, 2025

3. **Submitter information**

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4. **Identification of the subject device**

Trade Name:	“HsingChi” LipoSelector Disposable Fat Collection System
Common Name:	Lipoaspirate washing system for aesthetic body contouring
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.5040
Regulation Description:	Suction lipoplasty system
Product Code:	QKL
Device Class:	Class II

5. **Identification of the predicate device**

510(k) Number:	BK220691, Formally K101713
Predicate Trade Name:	LipoCollector II
Applicant:	Human Med AG
Regulation Number:	21 CFR 878.5040
Regulation Description:	Suction lipoplasty system
Product Code:	QKL
Device Class:	Class II

6. Indications for use

The “HsingChi” LipoSelector Disposable Fat Collection System (LS-1200) is a sterile medical device intended for the 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.

7. Device description

The “HsingChi” LipoSelector Disposable Fat Collection System (hereafter LipoSelector) is designed for fat harvesting and filtering purpose.

The main structure of LipoSelector: Canister (1200c.c), filter basket, side port and filter mesh, it does not contact with the patient body directly.

LipoSelector is a completely closed system and undergoes ethylene oxide (EO) sterilization, ensuring that the entire liposuction process is free from contamination.

The function principle of LipoSelector in medical institutions typically involves the use a liposuction system to aspirated fat from a patient's body, which is then collected and processed in a canister. The filtration gap of the filter basket is 3.0 mm, larger tissue strands of the aspirate are caught in the filter basket. Turn off the suction machine when you stop the harvesting, then proceed with the decant procedure (around 8-10 mins) until tumescent and fat separation. The tumescent fluid and water are then drained through the side port. The 300 μm filter mesh is fine enough to effectively further separate impurities such as broken fat and blood through the bottom port.

Its disposable nature allows each patient to have their own LipoSelector, eliminating the risk of infection. This also spares nursing staff from the burden of cleaning and sterilizing the fat collection, simplifying the liposuction process.

8. Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, “HsingChi” LipoSelector Disposable Fat Collection System.

- **Biocompatibility testing**

  The biocompatibility evaluation for the subject device was in accordance with the FDA Biocompatibility guidance (Use of International Standard ISO10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”).

  We have executed the following test. Test results meet the acceptance criteria.

  - Biological evaluation plan and report (ISO10993-1)
  - In vitro Cytotoxicity Test (ISO10993-5)
  - Guinea Pig Skin Sensitization Study (ISO10993-10, ISO10993-12)
  - White Rabbit Intracutaneous Irritation Test (ISO10993-10, ISO10993-12)
  - Acute Systemic Injection Study (ISO10993-11, ISO10993-12)
  - Pyrogen Study in White Rabbits (ISO10993-11, ISO10993-12, USP<151>)
  - Hemolysis Test (ISO10993-4, ASTM F756, ASTM F619)

- **EO Sterilization validation report**

  A series of tests, including bioburden test, EO/ECH/EG residual test, sterility test has been conducted to validate the EO sterilization of the subject device. Test results showed the validation meet the requirements of ISO 11135 and the achievement of the required sterility assurance level (SAL) of 10^{-6}.

- **Package integrity testing report**

  A series of tests was conducted on the subject device after 3 years of accelerated aging to validate package integrity, including visual inspection, package burst test, package creep test, dye penetration test, seal strength test, sterility test has been conducted to validate the package integrity. Test results showed the visual inspection package seal and package integrity of the sterile barrier system can meet the requirements, in accordance with ASTM F1980-16 and ASTM F1886/F1886M. And the package burst test, package creep test, dye penetration test and seal strength test of the sterile barrier system can meet the requirements of relating standards, including ASTM F1140/F1140M-2013, ASTM F88/F88M-15, and ISO11737-2: 2019.

- **Package integrity testing during shipping and handling**

Validation of package integrity during shipping and handling was conducted in accordance with ASTM D4332-22 and ASTM D4169 requirements. A series of tests were conducted on the subject device, including visual inspection, package burst test, package creep test, dye penetration test, seal strength test, sterility test to validate the package integrity. Test results showed the visual inspection of the sterile barrier system can meet the requirements, in accordance with ASTM F1886/F1886M-16. And the package burst test, package creep test, dye penetration test, seal strength test and sterility test of the sterile barrier system can meet the requirements of relating standards, including ASTM F1140/F1140M-13(R2020), ASTM F1929-23, ASTM F88/F88M-23, and ISO11737-2: 2019.

- **Reliability and performance testing**

  A series of safety and tests were conducted on the subject device. Testing are conducted to support the shelf life of three years when stored at 25 ± 2 °C, RH of 45%.

  - Performance test of Fat filtration
  - Performance test of Visible
  - Performance test of Air Leakage
  - Performance test of Filtering
  - Performance test of Connector
  - Performance test of Foam Preventing
  - Test for Container Strength
  - Physical and Chemical Analysis
    (e.g. pH-value, Residue on evaporation, Heavy metals, Phthalates content test, Reducing (oxidizable) matter, UV absorption)

All the test results demonstrate **"HsingChi" LipoSelector Disposable Fat Collection System** meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

9. Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

10. Substantial equivalence comparison

"HsingChi" LipoSelector Disposable Fat Collection System submitted in 510(k) files is substantially equivalent in intended use, safety and performance to the FDA cleared LipoCollector II (BK220691). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	**"HsingChi" LipoSelector Disposable Fat Collection System**	**LipoCollector II**	
510(k) No.	**BK251197**	**BK220691**	
Product code	QKL	QKL	Same.
Product class	2	2	Same.
Indications for use	The "HsingChi" LipoSelector Disposable Fat Collection System (LS-1200) is a sterile medical device intended for the 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.	The **LipoCollector II** is for harvesting, filtering and transferring of autologous fat tissue for aesthetic body contouring.	Similar.
User population	It is designed to be operated by trained medical staff.	It is designed to be operated by trained medical staff.	Same.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	**“HsingChi” LipoSelector Disposable Fat Collection System**	**LipoCollector II**	
510(k) No.	**BK251197**	**BK220691**	
Environment of use	It is intended for use in healthcare facilities.	It is intended for use in healthcare facilities.	Same.
Interaction with patient / Anatomical location of use	It will not contact with patient directly. The anatomical location will be determined by the medical staff based on clinical needs.	It will not contact with patient directly. The anatomical location will be determined by the medical staff based on clinical needs.	Same.
Design principles	Utilizing vacuum (liposuction devices) to aspirate adipose tissue from the patient and subsequently transport the adipose tissue through a tube into a collection container that contains a filtering mechanism to allow fluids to pass, but retains the adipose tissue within the container. They all consist of a polymeric tissue collection container with a filter unit within the chamber, and all have connection ports on the superior ends of the collection container for the attachment of suction tubing.	Utilizing vacuum (liposuction devices) to aspirate adipose tissue from the patient and subsequently transport the adipose tissue through a tube into a collection container that contains a filtering mechanism to allow fluids to pass, but retains the adipose tissue within the container. They all consist of a polymeric tissue collection container with a filter unit within the chamber, and all have connection ports on the superior ends of the collection container for the attachment of suction tubing.	Same.
Filter design	Double filter	Double filter	Same.
Mesh filter	300 μm	Three sizes of mesh filters are supplied with the LipoCollector II (200 μm, 250 μm and 315 μm).	Different. The difference doesn’t raise any new issues of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	**“HsingChi” LipoSelector Disposable Fat Collection System**	**LipoCollector II**	
510(k) No.	**BK251197**	**BK220691**	
Limitation of suction machine	Maximum vacuum 900mbar	Not setting the maximum vacuum	Different. We have conducted testing to validate the strength of the collection container is not imploding, crack. The difference doesn’t raise any new issues of substantial equivalence.
Material	PETG, HDPE, PP, PC	Made by polycarbonates (PC), stainless steel	Different. Both devices are Fulfill ISO10993 requirement. The difference doesn’t raise any new issues of substantial equivalence.
Sterilization method	EO Sterilization	EO Sterilization	Same.
Volume Range	1,200ml	1,000ml	Different. The difference doesn’t raise any new issues of substantial equivalence.
Properties	Single use only and closed system	Reusable	Different.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	**“HsingChi” LipoSelector Disposable Fat Collection System**	**LipoCollector II**	
510(k) No.	**BK251197**	**BK220691**	
			The difference doesn’t raise any new issues of substantial equivalence.

11. Similarity and difference

The “HsingChi” LipoSelector Disposable Fat Collection System has been compared with the LipoCollector II (BK220691). The subject device has the same intended use, environment of use, user population, interaction with patient / anatomical location of use, sterilization method, design principles as the predicate devices.

Although the reuse type, size of mesh filter, volume range and limitation of suction machine are different between the subject device and predicate devices. The subject device has undergone a series of testing, and the results passed the acceptance criteria defined by the testing standards used. It has proven the differences between the subject device and the predicate device do not raise any new issues on safety and effectiveness. The subject device is substantially equivalent to the predicate devices as it claims.

12. Conclusion

The subject device has tested safety and performance, and the test results complied with the test requests. Therefore, the differences between subject device and predicate device do not raise any problems of safety or effectiveness. We, HsingChi Medical Ltd., believe that “HsingChi” LipoSelector Disposable Fat Collection System is substantially equivalent to the predicate device.