HUMAN MED AG
Attention: Phil Triolo
86 Skycrest Ln
Salt Lake City, UT 84108

February 9, 2023

Re: BK220691 (Formally K101713)
Trade/Device Name: LIPCOLLECTOR II
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Triolo:

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 June 29, 2010. 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, Hosna Keyvan by email at hosna.keyvan@fda.hhs.gov.

Sincerely,

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

Enclosure

510(k) Summary LipoCollector II complete set

This 510(k) Summary for the LipoCollector II complete set meets the requirements of 21 CFR § 807.92

Date: 2010-05-28

JUN 29 2010

1. Submitter Information

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2. Name of Device:

Common Name:	Suction Lipoplasty System
Proprietary Name:	LipoCollector II complete set
Classification:	Class II - 21 CFR § 878.5040
Product Code:	MUU
Indications for use:	Aesthetic body contouring
Intended use:	Harvesting, filtering and transferring of autologous fat tissue.

3. Name of predicate device(s)

- Cytori AFT System; Cytori Therapeutics Inc - Product Code MUU; 510(k) number K072587
- Lipokit; Medi-Khan (USA) Inc - Product Code MUU; 510(k) number K083455
- Lipivage; Genesis Biosystems, Inc. - 510(k) number unknown

4. Description of the new device

The LipoCollector II complete set consists of an autoclavable polymeric tissue collection container with a stainless steel lid and pre-filtering basket, and a disposable set including mesh filters, O-rings and inner tubing. The LipoCollector II complete set also includes a stainless steel extraction cannula (single-use) for withdrawal of the collected fat from the collection container. From the extraction cannula, the fat can be directly transferred to a Luer-Lock-syringe (not part of the LipoCollector II complete set) for autologous fat transfer.
The intended use of the LipoCollector II complete set is to filter and collect the aspirated fat tissue for subsequent transfer of the autologous fat into subcutaneous fat tissues during the same procedure.

The LipoCollector II complete set is used together with FDA cleared devices (such as vaccuum devices, tubings, and syringes), for example suction lipoplasty devices (Product Code MUU, Regulation Number 21 CFR 878.5040), and syringes (e.g. 50 cc syringes, Luer-Lock, Product Code KYX). The aspirated fat gets transferred from the aspiration device to the collection container by the application of vacuum. The vacuum is generated by the aspiration device (e.g. suction lipoplasty device).

The LipoCollector II complete set serves to filter fatty and adherent tissue from the aspirate which is extracted during liposuction. The separated water (saline) gets transferred to the waste container of the aspiration device via a tube by the application of vacuum which is generated by the aspiration device. From the LipoCollector II collection container, the harvested fat is being removed by the extraction cannula, and then transferred into a syringe for autologous fat transfer into the desired body area(s).

The filtering of the aspirate with the LipoCollector II complete set is done predominantly using buoyancy and gravity. A special filter unit, comprising a stainless steel wire fabric with a mesh/hole size from 200 µm to 315 µm, captures the appropriate fat particles in a sterile collection container in such a way that only the saline rinsing solution ends up in the suction (waste) container provided. All parts are sterile and air contact to the fat from outside is avoided due to the closed system design of the LipoCollector II.

Function principles

The filtering of the aspirate with the LipoCollector II complete set is done predominantly using buoyancy and gravity. The suction of the liposuction system bypasses the previously collected aspirate via the integrated bypass. This means that the fatty tissue that has been suctioned off is handled as gently as possible.

The main principle behind the function of the LipoCollector II complete set is the initial separation of liquid and lipocytes due to the physical buoyancy. The less dense fat floats on the liquid which is concurrently and continuously suctioned off. In doing so the filter is constantly rinsed with liquid which reduces blockage of the filter mesh.

The LipoCollector II complete set is equipped with a stainless steel basket that acts as a pre-filter. By turning the lid of the LipoCollector II, the basket is positioned precisely beneath the opening of the connection labelled PATIENT, ensuring that incoming aspirate first runs through the basket. Larger strands of connective tissue are retained in the grates of the basket, which reduces blockage of the mesh filter and/or cannula.

Mesh filters: Three sizes of mesh filters are supplied with the LipoCollector II (200 µm, 250 µm and 315 µm).

Closed system filtration

The LipoCollector II complete set which is to be used under sterile conditions in the operating room represents a closed system. The LipoCollector II remains in a sterile field at all times, thus reducing the risk of infection. Also, the risk of contamination is lowered because the fat never leaves the closed sterile LipoCollector II collection container until re-injection.

Using the LipoCollector II complete set decreases the number of steps a physician must take to process the fat for autologous fat transfer (e.g. there are no extra steps of transferring the harvested fat between different containers or of subsequent centrifugation required). The LipoCollector II complete set allows collection and filtering in one step in one closed system container, and thereby maintaines the sterility of the harvested fat until the fat is transferred .

Extraction cannula of the LipoCollector II

The included sterile extraction cannula is used to withdraw the harvested fat from the LipoCollector II. The filtered aspirate is withdrawn from the collection container by the extraction cannula while keeping the lid of the LipoCollector II closed.

5. Intended Use

The intended use of the LipoCollector II is the harvesting, filtering and transferring of autologous fat tissue.

6. Summary of technological characteristics of the new device in comparison to those of the predicate devices

The LipoCollector II complete set shares indications, intended use and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to premarket devices: Cytori AFT System (K072587), Lipokit (K083455) and Genesis Biosystems Lipivage (510(k) number unknown).

The LipoCollector II complete set and the predicate devices are substantially equivalent with respect to their indication for use and their intended use, as they are all intended for the same procedure of harvesting, filtering and transferring of autologous fat tissue.

Design and Materials

The design and materials of the LipoCollector II complete set and the predicate devices (Cytori AFT System (K072587), Lipokit (K083455) and Genesis Biosystems Lipivage (510(k) number unknown)) are substantially equivalent, as they share the major design principles of utilizing vacuum (liposuction devices or house vacuum) 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.

In summary, the design and materials of the LipoCollector II complete set and its predicate devices (Cytori AFT System (K072587), Lipokit (K083455) and Genesis Biosystems Lipivage (510(k) number unknown)) are substantially equivalent, as they are all polymer constructed with surgical stainless steel components for direct patient contact, with collection containers which are operated manually, and utilizing varying sources of vacuum to withdraw and collect saline fluids containing fat tissue, from the body.

The LipoCollector II complete set is substantially equivalent to the above mentioned predicate devices, as 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, and stainless steel cannulae that contact the patient, and connection ports to connect the vacuum tubing that draws vacuum and carries waste to the waste container.

Like the above mentioned predicate devices, the LipoCollector II complete set decreases the number of steps a physician must take to process the fat for autologous fat transfer. When using the LipoCollector II complete set the fat remains in the sterile container at all times until immediately before reinjection, thus reducing the risk of contamination. The LipoCollector II complete set allows collection and filtering in one step in one collector.

7. Summary of compliance tests according to recognized standards

Design and Manufacturing Process Control Activities

human med AG has implemented a Quality Management System in accordance to DIN EN ISO 13485 and to the Council Directive 93/42/EEC on medical devices.

All design and manufacturing control activities for the LipoCollector II complete set are in accordance to section 7.3 of DIN EN ISO 13485 and to the Code of Federal Regulations (CFR) Title 21, Section 820.30.

The design and manufacturing activities of the LipoCollector II complete set all comply with the requirements of DIN EN ISO 10079-1:2009, CSA Z 168.11-94, ISO 2768-1:1989, ISO 2768-2:1989, ISO 7153-1:1991/Amd.1:1999 and ISO 9626:1991/Amd.1:2001.

For **product labeling** of the LipoCollector II complete set the requirements according to ISO 15223-1 are applied. The regulations of FDA 21 CFR 801.1, Device Labeling Guidance, and the Guidance for Labeling of the Canadian MDR were examined for special requirements regarding product labeling and product information.

Acceptance criteria for verification and validation testing of the device are based upon the approved product design specifications, including any additional design requirements imposed by Risk Management Process. Acceptance criteria for the LipoCollector II complete set include factors addressing product function, product safety, instructions for use, and packaging. All requirements of ISO 14971:2007 were met.

Biocompatibility Testing

Biocompatibility of the LipoCollector II complete set was examined for patient contact materials. The evaluation of the scope of biological testing was carried out as per EN ISO 10993-1:2009.

The intended use of the LipoCollector II complete set involves contact with tissue and bodily fluids for a period of less than 24 hours. To evaluate the biocompatibility of the LipoCollector II complete set, the following tests were necessary:
- Cytotoxicity test as per EN ISO 10993-5:2009-10, Annex C(metabolic cell activity)
- Cytotoxicity test as per EN ISO 10993-5 (membrane integrity)
- Epicutane test as per EN ISO 10993-10:2002-09,
- Quantitative detection of endotoxine in liquids and eluates as per EN ISO 10993-11:2006-08
- In vitro pyrogen test (IPT) as per EN ISO 10993-11:2006-08.

Results of the biological testings according to 10993-5, 10993-10 and 10993-11

Using the test material as mentioned before no cytotoxic effects could be found.
The tests for irritation and delayed-type hypersensitivity according to the DIN EN ISO 10993-10, 2002 were performed with an epicutane test with 10 volunteers.
No negative effects were observed. Also, with the LAL-Test (Limulus – Amebocyte – Test) no endotoxine could be detected in the eluate of the product.

Based on the submitted biocompatibility documentation, the LipoCollector II complete set can be regarded as biocompatible for the intended use of harvesting, filtering and transferring of autologous fat tissue.

Validation of ETO Sterilisation Cycle

The disposable products of LipoCollector II complete set are ETO sterilized by a CE and FDA registered contract sterilisation company. The sterilisation procedure to be used has been successfully validated by physical and microbiological methods in accordance to ISO 11135-1:2007. The evaluation reveals that the single-use products of the LipoCollector II collection container and the extraction cannula sterilized with the validated cycle and a sufficient sterilization safety level of 10^{-6} is guaranteed. The single-use products of the LipoCollector II complete set were evaluated for compliance with ISO 10993-7 for ETO residuals. The test results demonstrate compliance with the specifications.

Validation of Sterile Packaging

Packaging for the disposable products of the LipoCollector II complete set was successfully validated, and is compatible with the ETO sterilisation method. The packaging was qualified by testing to assure imperviousness to micro organisms. The validation of sterile packaging is in accordance to ISO 11607-1, 11607-2, DIN 58953 and EN 868-5.

Validation of Reprocessing

The reprocessing of the reusable parts of the LipoCollector II complete set (e.g. collection container, stainless steel lid and basket) has been successfully validated according to the requirements of AAMI/ANSI ST81:2004 "Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices".

8. Conclusions

Based upon the intended use, materials, and technological characteristics as presented in this notification, the subject device is shown to be substantially equivalent to the currently marketed predicate devices. There are no significant differences between the LipoCollector II complete set and its predicate devices relevant for safety and effectiveness with respect to the intended use of harvesting, filtering and transferring of autologous fat tissue

The intended use, the design, the materials and the collection principle of the LipoCollector II complete set are considered as substantially equivalent to its predicate devices (Cytori AFT System (K072587), Lipokit (K083455) and Genesis Biosystems Lipivage (510(k) number unknown)).

Also, the documentation for the LipoCollector II complete set on biocompatibility testing, sterilisation and further compliance testing according to recognized standards, as submitted in this 510(k) application, demonstrate that the LipoCollector II complete set can be regarded as safe and effective for the intended use of harvesting, filtering and transferring of autologous fat tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 29 2010

Human Med AG
% TUV SUD America Inc.
Mr. Stefan Preiss
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

Re: K101713
Trade/Device Name: LipoCollector II
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: June 11, 2010
Received: June 18, 2010

Dear Mr. Preiss:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101713

Device Name: LipoCollector II

Indications for Use:

Aesthetic body contouring

Intended Use:

Harvesting, filtering and transferring of autologous fat tissue

Prescription Use (Part 21 CFR 801 Subpart D) yes AND/OR Over-the-Counter Use (21 CFR 801 Subpart C) no

David Krone for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101713