

510(k) Summary

I. SUBMITTER

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II. DEVICE

Name of Device: PROCEDURE TRAY

Common or Usual Name: PROCEDURE TRAY

Proprietary Name /Device trade name: LG PT 15, LG PT 14, LG PT 12, LG PT 04, LG PT 03,
LG PT 02

Classification Name: 21 CFR 878.5040 Suction lipoplasty system

Regulatory Class: II

Product Code: QUB

III. PREDICATE DEVICE

Name of predicate device: KTA Adipose Treatment Kit

Manufacturer: Stemcis sas / Jointechlabs, Inc.

510(k) number: K190386 / BK220718-0

This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The medical device "Procedure Tray" (trade name LG PT XX) is a sterile, single-use kit that contain a selection of cannulas (for infiltration, fat harvesting and fat re-injection), syringes and transfer luer lock adaptors in one easy to use and locate kit.

The medical device is used in procedure for subcutaneous fat harvesting and re-implant in combination with "Lipogems process device" manufactured by Lipogems International Spa through mechanical micro-fragmentation.

The medical procedure includes the following steps:

- Harvesting of adipose tissue.
- Processing of the harvested tissue (involves only Lipogems process device)
- Injection of the tissue to the treatment site.

Six different configurations are available in order to meet patients' needs:

| REF / Code | Description | Kit composition | Quantity |
|-------------------|---|---|---|
| LG PT 12 | Lipoaspirate fat harvest and injection kit - 12 pieces (without cannulas) | <ul style="list-style-type: none"> - 20 ml aspiration syringe - 1 ml injection syringe - 10 ml syringe - 50 ml syringe - Luer Lock female to female connector - Tray L | <ul style="list-style-type: none"> 1 3 4 2 2 1 |
| LG PT 14 | Lipoaspirate fat harvest and injection kit - 14 pieces (2 cannulas) | <ul style="list-style-type: none"> - 20 ml aspiration syringe - 1 ml injection syringe - 10 ml syringe - 50 ml syringe - Luer Lock female to female connector - 17G infiltration cannula - 13G aspiration cannula - Tray L | <ul style="list-style-type: none"> 1 3 4 2 2 1 1 1 |
| LG PT 15 | Lipoaspirate fat harvest and injection kit - 15 pieces (3 cannulas) | <ul style="list-style-type: none"> - 20 ml aspiration syringe - 1 ml injection syringe - 10 ml syringe - 50 ml syringe - Luer Lock female to female connector - 17G infiltration cannula - 13G aspiration cannula - 20G injection cannula - Tray L | <ul style="list-style-type: none"> 1 3 4 2 2 1 1 1 1 |
| LG PT 04 | Lipoaspirate fat harvest and injection kit - 4 pieces (3 cannulas) | <ul style="list-style-type: none"> - 20 ml aspiration syringe - 17G infiltration cannula - 13G aspiration cannula - 20G injection cannula - Tray S | <ul style="list-style-type: none"> 1 1 1 1 1 |

| REF / Code | Description | Kit composition | Quantity |
|------------|--|---|-------------------------------------|
| LG PT 03 | Lipoaspirate fat harvest and injection kit - 3 pieces (3 cannulas) | <ul style="list-style-type: none"> - 17G infiltration cannula - 13G aspiration cannula - 20G injection cannula - Tray S | <p>1</p> <p>1</p> <p>1</p> <p>1</p> |
| LG PT 02 | Lipoaspirate fat harvest and injection kit - 2 pieces (2 cannulas) | <ul style="list-style-type: none"> - 17G infiltration cannula - 13G aspiration cannula - Tray S | <p>1</p> <p>1</p> <p>1</p> |

Table 1 – Brief description of the available configurations of "Procedure Tray"

Components brief description:

- 20 ml Suction Syringe with Male Luer Lock Connector and Four Position Plunger Lockout Device.
- 50 ml syringes with male Luer Lock connector.
- Female-female Luer Lock connectors, preassembled on the 50 ml syringes, designed to allow the transfer of biological material from the collection syringe to those necessary to use the processing device and from the latter to those necessary for the execution of the plant.
- 10 ml syringes with male Luer Lock connector, intended for the infiltration of the anaesthetic solution, for the loading of the processing device and for the extraction of the material processed by it.
- Syringes of 1 ml intended for replanting the microfragmented tissue.
- 17Gx185 mm cannula for infiltration with Luer-Lock connector, equipped with rounded tip and 6 orifices on its lateral surface, equipped with protective cap.
- 13Gx185 mm suction cannula with Luer-Lock connector, equipped with rounded tip and 5 suction orifices on its lateral surface, equipped with protective cap.
- 20Gx70 mm injection cannula, equipped with a rounded tip and an elongated lumen on the lateral surface, equipped with a protective cap.

All cannulas contained in LG PT 14, LG PT 15, LG PT 02, LG PT 03 and LG PT 04 "Procedure Tray" are cannulas with a rounded tip for manual use and are disposable, intended for use in general surgical procedures and particularly suitable for the collection and transfer of autologous adipose tissue. They should be used exclusively with the manual syringes contained in the same procedural tray. Each cannula is provided with a protector sheath and identified by a colour code:

Infiltration cannula 17Gx185 mm: Red

Aspiration cannula 13Gx185 mm: Blue

Injection cannula 20Gx70 mm: Yellow

The cannulas must not be used in combination with active devices of any type such as, for example, motorized suction or injection pumps.

The tray is produced by a mould of thermoformable material. Procedure tray allows each component to be housed in a defined position improving usability and ergonomic requirements during surgical procedure. Procedure tray is available in two different dimensions: Tray L used for codes LG PT 15, LG PT 14 and LG PT 12 and Tray S used for codes LG PT 02 LG PT 03 and LG PT 04.

The procedure tray provides slots for the decanting phase (i.e., to separate the aqueous phase, or emulsified oils, from the lipid phase of the content); in particular four slots for the vertical positioning of the 10 ml syringes and an inclined position for the 50 ml syringe.

"Procedure Tray" is sterile (sterilized with ethylene oxide gas) and it is intended for single patient use only.

V. INDICATIONS FOR USE

LG PT 15, LG PT 14, LG PT 12, LG PT 04, LG PT 03, LG PT 02 are intended for removal and transfer/reimplantation of autologous adipose tissue without further manipulation for aesthetic body contouring, within the same procedure. In combination with the Lipogems System these devices are intended for use in the following surgical specialties: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery.

The indications for use are the same of the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

| | Procedure Tray | Predicate Device BK220718-0/ K190386 |
|--------------------------------------|--|--|
| General description of device | The medical device "Procedure Tray" (trade name LG PT xx) contains a selection of cannulas (for infiltration, fat harvesting and fat reinjection), syringes and transfer luer lock adaptors in one easy to use and locate kit that is available in 6 different versions. | The KTA Adipose Treatment Kit range consists in a family of products which are designed to harvest, process with minimal manipulation and reinject small – KTAMICRO, KTAEASY, KTAMY – to large – KTAMACRO, KTAMACROMED, KTASPIN – volumes of autologous fat. Components: syringes with removable plunger, centrifuge tubes with filter, aspiration & fat injection cannula, fat injection syringes, skin puncture needles, and oil extraction syringe & needle. |
| Device components | Components of the most complete version of "Procedure Tray" LG PT 15: 20 ml aspiration syringe, 1 ml injection syringe, 10 ml syringe, 50 ml syringe, Luer Lock female to female connector, 17G infiltration cannula, 13G aspiration cannula, 20G injection cannula, Tray. | Components of KTAMACRO: 1 infiltration cannula (Ø 2.1 mm x 250 mm), 2 harvesting cannula 20 holes (Ø 3.0 x 3.5 mm x 250 mm) and (Ø 3.0 x 3.5 mm x 200 mm), 6 incremental syringes – 60 ml, 2 injection cannulas – 14G (Ø 1.7 – 2.1 mm x 200 mm) and (Ø 1.7 – 2.1 mm x 130 mm), 10 injection syringes – 10 ml, 2 needles – 18G / 18G NOKOR, 8 Luer-Lock caps, 1 nut to secure the rotor, 2 Luer-Lock connectors. |

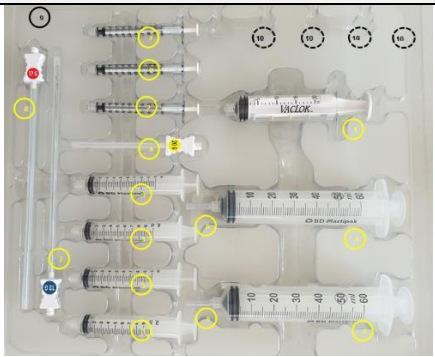

| | Procedure Tray | Predicate Device BK220718-0/ K190386 |
|---------------------------------|---|---|
| Representation of device |  |  |
| Materials of components | Syringes and connectors are made of plastic materials, needles and cannula are made of stainless steel. | Syringes composed of medical grade plastics, needles and cannula composed of steel. |
| Sterilization | Ethylene Oxide Gas (EtO) | Ethylene Oxide Gas (EtO) |
| Disposable/Reusable | Disposable, single use only | Disposable, single use only |
| Shelf-life | 5 years | 3 years |
| Packaging | The tray is packaged in a pouch made of LDPE transparent with insert in Tyvek 1073B | Tyvek sealing |

Table 2 – Comparison of technological characteristics between “Procedure Tray” and predicate device

“Procedure Tray” manufactured by Hydra Srl and the predicate device have the same intended use, general configuration, sterilization method, components materials and are both single use devices.

Technical differences are the following:

- “Procedure Tray” contains 3 cannulas: 17G, 13G and 20G while predicate device contains infiltration cannula (Ø 2.1 mm x 250 mm), harvesting cannula 20 holes (Ø 3.0 x 3.5 mm x 250 mm) and (Ø 3.0 x 3.5 mm x 200 mm), injection cannulas – 14G (Ø 1.7 – 2.1 mm x 200 mm) and (Ø 1.7 – 2.1 mm x 130 mm), needles – 18G / 18G NOKOR.
- “Procedure Tray” contains 20 ml aspiration syringe, 1 ml injection syringe, 10 ml syringe, 50 ml syringe, Luer Lock female to female connector while predicate device contains incremental syringes – 60 ml, injection syringes – 10 ml, Luer-Lock caps, nut to secure the rotor, Luer-Lock connectors.
- Shelf-life of “Procedure Tray” is 5 years while shelf-life of predicate device is 3 years.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for "Procedure Tray" was conducted in accordance with the guideline "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The device was classified as an external communicating device in contact with tissue for a limited contact duration (≤ 24 h).

The following tests were performed:

- Cytotoxicity
- Intracutaneous reactivity
- Acute systemic toxicity
- Lal test
- Pyrogen test
- Delayed hypersensitivity test (GPMT)

All results were compliant.

VIII. CONCLUSIONS

"Procedure Tray" is substantially equivalent to the predicate devices in Indications for Use, composition and design. It is as safe and as effective as the predicate. Hydra Srl considers "Procedure Tray" to be substantially equivalent to the predicate device.