FDA 510(k) Premarket Notification

Euromi S.A _ NLF Kit system.

510(k) Summary.

Device Name :	NLF system® kit 2
510(k) Owner & Manufacturer :	EUROMI S.A Zoning Industriel des Plenesses-11 rue des Nouvelles Technologies ANDRIMONT 4821 Belgium
510(k) Submitter and Contact :	Perrine BENOIT Quality Engineer Perrine.benoit@cerecare.fr +32(0)87292222
FDA Classification Name :	21 CFR Part 878 -General & Plastic Surgery 878.5040 - Suction lipoplasty system Classification product code: QKL (Class II) – Lipoaspirate Washing System for Aesthetic Body Contouring Secondary product code: QUB – Suction lipoplasty system for removal and transfer
Classifcation Panel :	General & Plastic Surgery
Common Name	Lipoplasty System
Predicate Device	BK220706 The Red Head Collection Device The Jordy Connection System

Device name	NLF System ® kit	The Red Head Miami Fat Supply
Device description	The NLF System ® - Sterile fat cell collection and re-injection kit is a sterile disposable collection kit used following lipoinfiltration for liposuction coupled with a lipofilling. The kit is intended to recover the adipocytes of a patient in order to reinject them into another zone of their body. The NLF System ® - Sterile fat cell collection and re-injection kit is a sterile single-use kit destined to be used by a healthcare professional. The NLF System ® - Sterile fat cell collection and re-injection kit is a medical device intended to assist practitioners during liposculpture or lipofilling procedures. The NLF System ® makes it possible to retain the fat directly in a micron filter to remove residue and obtain purified fat.	The Red Head is a single use, closed loop tissue collection device comprised of a medical grade canister, vacuum port, collection port, tissue port and cap intended to be used with standard liposuction aspiration to collect fatty tissue for aesthetic body contouring. As the tissue is harvested from the patient it enters the canister through the collection port on the canister lid. The physician removes waste materials from the canister by closing the valve on the center of the lid. The fatty tissue remains that can be withdrawn through the tissue port on the bottom center of the canister for autologous fat re-injection.

Picture of Product		
Intended Use:	The NLF System ® - Sterile fat cell collection and re-injection kits are used following lipoinfiltration during liposuction or lipofilling procedures. Liposuction is aimed at reducing the fat mass in one or more targeted areas of the human body for aesthetic or healing purposes. Lipofilling consists in transferring the fat from an area in the body into another in order to remodel or increase the volume of a body part.	The Red Head is used in the aspiration, harvesting, filtering and extraction of autologous adipose tissue for aesthetic body contouring
Technology Comparison	The NLF system kit employs the same technological characteristics as the predicate device.	The Red Head employs the same technological characteristics as the predicate device.
Suction Source	Aspiration Device	Aspiration Device
Volume range	Up to 1000mL	Up to 2500 mL
Shipped Sterile	Yes	No, sterilized by user prior to use
Sterility Assurance Level	10^{-6}	10^{-6}
Disposable or Reusable	Single Use, Disposable	Single Use, Disposable
Resterilization Method	Not Applicable	Not Applicable

Indications for Use :

The NLF SYSTEM® kit is indicated for:

• Removing tissues and/or liquids from the body following an infiltration of tumescent solutions, during surgical procedures, including liposuction, intended for aesthetic body contouring

• Injecting autologous adipose tissues, “lipofilling”, for aesthetic body contouring purposes

Device Description :

The NLF System ® - Sterile fat cell collection and re-injection kit is a sterile disposable collection kit used following lipoinfiltration for liposuction coupled with a lipofilling. The kit is intended to recover the adipocytes of a patient in order to reinject them into another zone of their body.

The NLF System ® - Sterile fat cell collection and re-injection kit is a sterile single-use kit destined to be used by a healthcare professional. The NLF System ® - Sterile fat cell collection and re-injection kit is a medical device intended to assist practitioners during liposculpture or lipofilling procedures.

The NLF System ® makes it possible to retain the fat directly in a micron filter to remove residue and obtain purified fat.

Intended use :

The NLF System ® - Sterile fat cell collection and re-injection kits are used following lipoinfiltration during liposuction or lipofilling procedures. Liposuction is aimed at reducing the fat mass in one or more targeted areas of the human body for aesthetic or healing purposes. Lipofilling consists in transferring the fat from an area in the body into another in order to remodel or increase the volume of a body part.

List of component :

-Single use specific cannula

-Sterile canister

-Cannula tubing

-Vacuum tubing

-Elbows

Predicate and Reference device comparison table :

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Substantial Equivalence Discussion :

The main difference between the subject device and predicate device is the sterility of the product. The NLF kit system is sterilized by the manufactured, with ethylene oxyde while the predicate product is not sterilized.

The NLF kit system is sold with a sterile cannula, while the predicate is sold with a syringe.

Conclusion for the Substantial Equivalence of the Device :

Based on the performance and comparison date contained within this submission, the Red Head and Jordy Connection System deems that the NLF kit system is substantially equivalent to the identified predicate device.