DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 24, 2017

Miami Fat Supply
% Ms. Ayanna Brown
Bgf Consulting
325 South Mcgee Ave.
Apopka, Florida 32703

Re: K161372
Trade/Device Name: The Red Head Collection Device, The Jordy Connection System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: May 9, 2016
Received: May 17, 2016

Dear Ms. Brown:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161372

Device Name
Red Head Collection Device and Jordy Connection System

Indications for Use *(Describe)*
The Red Head and Jordy Connection System is indicated for use as a liposuction adipose (fatty) collection system used in the aesthetic body contouring and collection of autologous adipose tissue. The Red Head and Jordy Connection System is intended to be used in the following surgical procedures:

- Aspiration of adipose (fatty) tissue
- Harvesting adipose (fatty) tissue
- Filtering adipose (fatty) tissue
- Extraction of autologous adipose (fatty) tissue

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Name:	**The Red Head and Jordy Connection System**
510(k) Submission:	K161372
Date of Submission:	January 25, 2017
510(k) Owner & Manufacturer:	Donnell Mark Jordan Miami Fat Supply Inc. 1510 Max Hooks Rd. #F Groveland, FL 34736 Telephone: 352-557-6979 Fax: 352-388-9447 miamifatsupply@gmail.com
510(k) Submitter and Contact:	Ayanna Brown BGF Consulting LLC 325 South McGee Avenue Apopka, FL 32703 Phone: 407-574-7195 Fax: 407-814-0127 ayanna@bgfconsulting.com
FDA Classification Name:	21 CFR Part 878- General and Plastic Surgery Subpart E - Surgical Devices Sec. 878.5040 Suction Lipoplasty System Class II Device Product Code MUU 21 CFR Part 880- General Hospital and Personal Use Subpart G - General Hospital and Personal Use Sec. 880.6960 Irrigation Syringe Class I (Sterile) Device Product Code KYZ
Classification Panel:	General and Plastic Surgery
Common Name:	Lipoplasty System
Predicate Device:	K092284 Lipisystems AquaVage (Product Code MUU) 21CFR 880.6960 Irrigation Syringe Classification (Product Code KYZ)

Indications for Use:
The Red Head and Jordy Connection System is indicated for use as a liposuction adipose (fatty) collection system used in the aesthetic body contouring and collection of autologous adipose tissue. The Red Head and Jordy Connection System is intended to be used in the following surgical procedures:

- Aspiration of adipose (fatty) tissue
- Harvesting adipose (fatty) tissue
- Filtering adipose (fatty) tissue
- Extraction of autologous adipose (fatty) tissue

Device Description:
Device Functions:

1. Single Use closed loop system collection device (same)
2. Canister contains ports on lids for interface between: Jordy Connection System to Canister and aspirator pump.
3. Connection system to connect tubing to interfaces
4. Funnel to enable fat to separate from fluids
5. Channel for fluid evacuation.
6. Toomey Syringe to extract fat from device.

Device Design:

1. Owner holds patent to predicate device and has improved performance and safety through this design.
2. Non-Sterile, Single Use
3. Canister able to withstand 30 in/Hg (18 in/Hg maximum vacuum used for collection of adipose (fatty tissue) for harvesting.
4. Tissue enters canister through collection port on canister lid.
5. Funnel perforation large enough for only adipose (fatty) tissue to be collected
6. Waste material is removed from canister by closing valve on center of lid.
7. Remaining adipose (fatty) tissue can be withdrawn through tissue port on bottom of center of canister for autologous adipose (fatty) tissue extraction.

Physical Properties and Materials Used:

1. Canister, Funnel and Outer Lid made from Polycarbonate
2. Evacuation spout and pinch clamps made from Polypropylene
3. Tubing made from silicone

Intended use of Device:
For use in aspirating subcutaneous fatty tissue including autologous fat collection.

Predicate and Reference device comparison table

Device Name	The Red Head Miami Fat Supply	Medical Device ResourceCorp. Lipisystems Aquavage ***Predicate Device***
Device Description	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.	The Lipisystems Aquavage consists of a plastic canister, silicone tubing, with a vacuum port, collection port and bottom tissue port and lid, intended to be used with a standard liposuction pump to collect fatty tissue for aesthetic body contouring. As the tissue is harvested from the patient it enters the canister via the port in the canister lid. The physician removes unwanted waste materials from the collection system via the vacuum port by closing the valve on the lid. This process leaves fatty tissue that can be transferred to syringes via the tissue port for autologous fat reinjection.
Picture of Product		
Intended Use:	The Red Head is used in the aspiration, harvesting, filtering and extraction of autologous adipose tissue for aesthetic body contouring	The Aquavage is used in the aspiration, harvesting, filtering and extraction of autologous adipose tissue for aesthetic body contouring
Technology Comparison	The Red Head employs the same technological characteristics as the predicate device.	The Lipisystems Aquavage employs the same technological characteristics as the predicate device.
Suction Source	Aspiration Device	Aspiration Device
Volume	Up to 2500 mL	2000 cc or 1200cc

Range		
Shipped Sterile	No, sterilized by user prior to use	Yes
Sterility Assurance Level	10^{-6}	10^{-6}
Disposable or Reusable	Single Use, Disposable	Single Use Disposable
Resterilization Method	Not Applicable	Not Applicable

Substantial Equivalence Discussion:
The Subject and Predicate device are identical in terms of function and performance. Performance testing has demonstrated that the subject device operates as designed and functions as intended. Performance tests include Assembly Verification, Leak Testing, Canister Implosion, Tubing Collapse and Pull Off Force Testing. Biocompatibility was evaluated in accordance with ISO 10993 - Biological Evaluation of Medical Devices. Tests for cytotoxicity, intracutaneous reactivity, sensitization, and acute systemic toxicity were completed and passed. The subject device of this submission is indicated for collection and transfer of autologous adipose tissue. Tissue viability testing found no adverse effect on adipose tissue with use of the subject device. The minimally manipulated nature of such tissue in the subject device and the predicate device form the basis of substantial equivalence.

Conclusion for the Substantial Equivalence of the Device:
Based on the performance and comparison data contained within this submission, Miami Fat Supply deems that the Red Head and Jordy Connection System is substantially equivalent to the identified predicate device.