U.S. FOOD & DRUG ADMINISTRATION

THE GID GROUP INC.
Attention: William Cimino
901 Front Street
Louisville, CO 80027
Email Address: (b) (6)@theGIDgroup.com

February 9, 2023

Re: BK220695 (Formally K120902)
Trade/Device Name: GID 700
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Cimino:

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 August 15, 2012. 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

K 120902

1 of 2

510(k) Summary

AUG 15 2012

Submitted by	The GID Group Inc. 578 W. Sagebrush Ct. Louisville, CO 80027 303-952-4901

Contact Person	Lewis Ward L.W. Ward and Associates, Inc. 4655 Kirkwood Court Boulder, CO 80301 303-530-3279 lwward@qwest.net

Date Prepared	July 11, 2012

Product Name	GID 700 Tissue Canister

Classification	System, Suction, Lipoplasty Product Code: MUU Regulation Number: 878.5040 Device Class 2 General Plastic Surgery Panel

Indication for Use Statement	The GID 700 is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation. The GID 700 is intended for use in the following surgical specialties when aspiration of soft tissue is desired: plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

Technological Characteristics	The GID Group's GID 700 device is a sterile, single use 700 ml canister and accessories used to receive and filter tissue from lipoplasty procedures. When the tissue is deposited into the canister, it is filtered through a mesh filter to capture the tissue. The vacuum source is user or institution supplied. Various ports on the canister provide access to the vacuum source, receives the harvested tissue, vent the canister during the wash process, and transfer the filtered tissue.

Test Data	Canister vacuum Implosion Test – passes Tubing connection, tensile strength – passes Mechanical plugging testing – passes Biocompatibility – meets ISO 10993 requirements Pyrogen Test – non-pyrogenic

Features	**GID 700**	**Shippert Tissu-Trans Filtron 1000**
Indication for Use	Used in the aspiration, harvesting, filtering, and transferring of autologous tissue.	Used in the aspiration, harvesting, filtering, and transferring of autologous tissue.
Manufacturer	The GID Group, USA	Shippert Medical Technologies Corp.
Product Code	MUU, Class 2 General and Plastic Surgery Panel	MUU, Class 2 General and Plastic Surgery Panel
Regulation Number	878.5040 Suction Lipoplasty System	878.5040 Suction Lipoplasty System
Use Mode	Single use, disposable, sterile. Unit remains assembled throughout entire process.	Single use, disposable, sterile. Unit remains assembled throughout entire process.
Sterilization Method	Electron Beam Irradiation ISO 11137	Radiation
Canister Construction	Polymer materials, closed system filtration, and disposable tubing sets. Manual stir mechanism.	Polymer materials, closed system filtration, and disposable tubing sets
Source of Energy	User supplied vacuum	User supplied vacuum
Filtering	200 micro mesh filter to retain tissue	400 micron mesh filter to retain tissue
Accessory	None. Institutions provide collection trap.	None. Institutions provide collection trap.
Mechanical Testing	- Implosion test: Passes - Tubing Connection, Tensile Strength: Passes - Mechanical Plugging: Passes	- Implosion test: Passes - Tubing Connection, Tensile Strength: Passes - Mechanical Plugging: Passes
Biocompatibility	Meets ISO 10993 External Communicating Device, Contact < 24 hours	Meets ISO 10993 External Communicating Device, Contact < 24 hours
Canister Size	700 ml	1000 ml
Canister Ports	Suction, vent, input, extraction	Suction, vent, input, extraction

Substantial Equivalence	The GID 700 is substantially equivalent to the Shippert Tissu-Trans Filtron 1000 canister (K092482) manufactured by Shippert Medical based on design, materials, and testing.

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

AUG 15 2012

The CID Group, Incorporated
% L.W. Ward and Associates, Incorporated
Mr. Lewis Ward
Consultant
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K120902
Trade/Device Name: GID 700
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: July 18, 2012
Received: July 19, 2012

Dear Mr Ward:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

Device Name: GID 700

Indications for Use:

The GID 700 is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.

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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MM

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

510(k) Number K120902