BIOMET INC.
Attention: Lonnie Witham
56 East Bell Dr., Box 587
Warsaw, IN 46581-0587

February 9, 2023

Re: BK220690 (Formally K100114)
Trade/Device Name: FAT CONCENTRATION SYSTEM
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Whitman:

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 September 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, Julia Russell at 240-704-0618 or by email at Julia.Russell@fda.hhs.gov.

Sincerely,

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

Enclosures

K100114

510(k) Summary

Preparation Date: October 16, 2009

SEP 29 2010

Applicant/Sponsor: Biomet Biologics, Inc., P.O. Box 587, Warsaw, IN 46581
Contact Person: Lonnie Witham
Proprietary Name: Vortech™ Adipose Transfer System (VATS)
Common Name: Fat Concentration System
Classification Name: Suction Lipoplasty System
MUU (21 CFR 878.5040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K072587	Cytori AFT System, Cytori Therapeutics, Inc.
K081848	Lipose Fat Transfer System, Lipose Corporation

Device Description:
The VATS System includes a disposable fat concentrator, reusable portable tabletop base unit, and single-use piston syringes.

Intended Use:
The Vortech™ Adipose Transfer System (VATS) is used in medical procedures involving the harvesting and transferring of autologous fat tissue. The VATS System is used for concentrating fat harvested with a legally marketed lipoplasty system. The VATS System is intended for use in the following surgical specialties when the concentration of adipose tissue is desired.

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery
-

Summary of Technologies:
The manufacturing methods, components and materials used for the VATS System have been used in devices previous-cleared for commercial distribution.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The testing included verification that the output of the Vortech™ Adipose Transfer System (VATS) is substantially equivalent to the Viafill™ System (Lipose Corp.) predicate device by direct comparison. Test results for both percent volume reduction and percent cell viability show that the VATS System is substantially equivalent to the Viafill™ System, a currently marketed predicate device. The results indicated that both devices were functional within their intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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

SEP 29 2010

Biomet Biologics, LLC
% Mr. Lonnie Witham
Regulatory Affairs Consultant
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K100114
Trade/Device Name: Vortech™ Adipose Transfer System (VATS)
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: August 30, 2010
Received: August 31, 2010

Dear Mr. Witham:

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,

For Peter D.R.

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

Enclosure

K100114

Indications for Use

510(k) Number (if known):_____ SEP 29 2010

Device Name:

Indications for Use: Vortech™ Adipose Transfer System (VATS)

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- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100114

K100114

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SEP 29 2010

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