Black & Black Surgical, Inc.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

June 9, 2021

Re: K170629
Trade/Device Name: Vitruvian Infiltration Pump
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Mark Job:

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 June 22, 2017. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 22, 2017

Black & Black Surgical, Inc.
% Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K170629
Trade/Device Name: Vitruvian Infiltration Pump
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: June 16, 2017
Received: June 20, 2017

Dear Mr. Job:

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,

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)*

Device Name
Vitruvian Infiltration Pump

Indications for Use *(Describe)*

Aesthetic body contouring

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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770-414-4880

510(k) Summary

This summary of 5 10(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **Submitter Information:**
   Prepared: 02/10/2017

   Est. Reg. #: 3006142527

   Norman M. Black, CEO, normanblack@blackandblacksurgical.com
   Black & Black Surgical, Inc.
   5238 Royal Woods Parkway
   Suite 170
   Tucker, GA 30084
   770-414-4880 T / 770-414-4879 F

   Contact Person: Cynthia Rees, Regulatory Engineer, crees@blackandblacksurgical.com

2. **Name of Device:** Vitruvian Infiltration Pump

   Proprietary Name: Vitruvian Infiltration Pump

   Common Name: Infiltration Pump

3. **Classification:** Suction Lipoplasty System, Class II - 21 CFR §878.5040 (1998)

4. **Product Code:** MUU

5. **Substantial Equivalence:**
   The Vitruvian Infiltration Pump is believed to be substantially equivalent to the infiltration devices listed below in terms of use, design, operating principles, materials and performance.

HK Surgical:	K031432
MOELLER MEDICAL GMBH & CO. KG:	K072793

6. **Device Description:**
   The B89055 Vitruvian Infiltration Pump is intended to be used for aesthetic body contouring. Normal use includes general tumescent infiltration. It has a self-adjusting power converter which works with either 100V or 240V currents, and includes a pneumatic foot-switch and self-adjusting tubing guide to prevent tubing slippage during operation. It has a fully adjustable flow rate between 0 mL/min and 475 mL/min.

The Vitruvian Infiltration Pump is a pre-assembled device consisting of:

- **Housing**: ABS Plastic
- **Power Operation**: 100-240VAC, 50-60Hz, 1.8-1.0A
- **Head**: 3 roller peristaltic action
- **Control**: Knob used to set mL/min
- **Display**: LED
- **Foot Switch**: Air Powered ON/OFF
- **Power Cord**: Yes

The infiltration pump does not contact the patient.

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7. Indications for Use: Aesthetic Body Contouring

8. **Comparison to Predicate**

Item	**Predicate Device 1**	**Predicate Device 2**	**Subject Device: #1**	**Similarity 1/2**
Device name	HK Klein Surgical KIP-II Infiltrator	Liposat Basic	Vitruvian Infiltration Pump	N/A
Device Manufacturer	HK Surgical	Moller Medical GmbH	Black & Black Surgical, Inc.	N/A
510(k) Reference	K031432	K072793	Not yet assigned	N/A
FDA Product Code	FRN	MUU	MUU	Different/Same
FDA Classification	Suction Lipoplasty System	Suction Lipoplasty System	Suction Lipoplasty System	Same
FDA Regulation #	880.5725	878.5040	878.5040	Different/Same
Indication for Use / Intended Use	This Infiltration Pump is used to cause a flow of fluid from an IV bag into patient in a manner controlled manually by a health care professional. The Klein Pump is not intended to be used as an IV infusion pump.	Aesthetic Body contouring	Aesthetic body contouring.	Similar/ Same
Specific drug, biologic use	N/A	N/A	N/A	Same
Administrative sets & reservoir	N/A	N/A	N/A	Same
Mechanical Operation				
Item	**Predicate Device**	**Predicate Device**	**Subject Device**	**Similarity**
Pump type	Peristaltic	Peristaltic	Peristaltic	Same
AC Power input	115/230V, 60/50Hz	230 VAC, 50Hz	110-240V, 50/60Hz	Similar
Maximum flow rate	600 RPM /1000 mL/min	200 mL/min	475 mL/min	Different
Safety/Alarm functions	N/A	N/A	N/A	Same
Pressure control	Knob to control RPM	Pressure Button	Knob to control RPM	Same/Similar
Footswitch	Air Powered	Air Powered	Air powered	Same
Display	Gage	LED	LED	Different/similar
Pumping Mechanism	One Roller	Two Rollers	Three Rollers	Similar
Housing / Materials	Powder Coated Steel	High Performance Plastic	ABS plastic	Different / Similar
Weight	10 lbs	2.5 kg	7.2 lbs	Similar
Dimensions	12” x 9” x 6”	6.7” x 7.8” x 5.5”	11” x 8” x 7”	Similar

9. **Performance Testing**

The device complies with the following standards:

Tested/Evaluated Standard	Results
IEC 60601 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	Complies
ANSI/AAMI ES60601-1:2005 +A1:2012 + A2:2010, ed. 3.1	Complies
CAN/CSA C22.2 No. 60601-1 Ed. 3 + A1(2014)	Complies
EN 60601-1:2006 + A1:2013 (2013) + A11 (2011), + A12 (2014)	Complies
IEC 60601-1-2:2007 (3rd Edition)	Complies

Performance Testing Performed at Manufacturing Facility:

- Vitruvian Infiltration Pump Flow Rate Display Calibration – Pass

10. **Substantial Equivalence Conclusion:**
Based on the information contained in this submission, it is concluded that the Vitruvian Infiltration Pump is substantially equivalent to the identified predicate devices, which are already in interstate commerce within the USA.