



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

July 26, 2016

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

Re: K161722  
Trade/Device Name: Vitruvian Ultimate Aspirator  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction Lipoplasty System  
Regulatory Class: Class II  
Product Code: MUU  
Dated: July 18, 2016  
Received: July 19, 2016

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

## Indications for Use

510(k) Number (if known)

K161722

Device Name

Black & Black Vitruvian Ultimate Aspirator

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.

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## **510(k) Summary**

**This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.**

1. **Submitter Information:**

Prepared: June 15, 2016

Est. Reg. #: 3006142527

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Contact Person: Cynthia Rees, Regulatory Engineer, [crees@blackandblacksurgical.com](mailto:crees@blackandblacksurgical.com)

2. **Name of Device:** Vitruvian Ultimate Aspirator

**Proprietary Name:** Vitruvian Ultimate Aspirator

**Common Name:** Aspirator Pump, Liposuction Aspirator, Power Suction Pump

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

4. **Product Code:** MUU

5. **Substantial Equivalence:**

The Vitruvian Ultimate Aspirator is substantially equivalent to the aspiration device listed below in terms of use, design, operating principles, materials and performance.

Byron Medical: K981215

6. **Device Description:**

The Vitruvian Aspirator is a pre-assembled device consisting of:

- **Housing:** Powder Coated Steel
- **Vacuum Pump:** Dual ½ hp dual voltage rocking piston motor with Maximum Suction flow rate of 125PSI, 6.4 cfm, 27.5in HG(711 mm of Hg)
- **Vacuum Meter Display:** The device displays the vacuum levels digitally. The software does not control the unit in any way and does not accept any input.
- **Power Operations:** 120/230 volt 50/60hz
- **Control:** Pressure control valve located on the face of the device with rotary control knob with both LED numerical and Color Graphic LED display
- **Footswitch:** Dual activated air powered
- **IV Pole**
- **Filter:** Bacterial filter having a pore size of 0.3 microns or less.

7. **Indications for Use:** Aesthetic body contouring.

### 8. Comparison to Predicate

Item	Predicate Device	Subject Device	Similarity
Device name	PSI-TEC Aspirator	Vitruvian Ultimate Aspirator	N/A
Device Manufacturer	Byron Medical. Inc.	Black & Black Surgical, Inc.	N/A
510(k) Reference	K981215	K161722	N/A
FDA Product Code	MUU	MUU	Same
FDA Classification	Suction Lipoplasty System	Suction Lipoplasty System	Same
FDA Regulation #	878.5040	878.5040	Same
Indication for Use / Intended Use	Aesthetic body contouring	Aesthetic body contouring	Same
<b>Mechanical Operation</b>			
Item	Predicate Device	Subject Device	Similarity
Pump type	Two cylinder piston	Two cylinder piston	Same
AC Power input	115-240V, 60-50Hz	120V/230V, 50/60Hz	Similar
Maximum Vacuum	28 in of Hg	27.5 in of Hg	Similar
Maximum flow rate	4.75 CFM	6.4 CFM	Similar
Sound level	52 dB	50 dB	Similar
Pressure control	Knob to control vacuum	Knob to control vacuum	Same
Footswitch	Dual activated air powered	Dual activated air powered	Same
Display	Vacuum gage	Vacuum gage w/LED color graphic read out	Different
Safety Features (over flow valve)	Manual (canister)	Manual (canister)	Same
Housing	Powder Coated Steel	Powder Coated Steel	Same
IV Pole for Solutions:	Yes	Yes	Same
Filter port:	Yes	Yes	Same
Filter	0.3 Micron	0.3 Micron	Same
Dimensions	20.18 in (H) x 22.96 in (D) x 18.32 in (W)	18 in (H) x 18 in (W) x 38 in (H)(45cm x 45cm x 97cm)	Similar
Weight	80 lbs. /36.288 Kilograms	100 lbs	Similar

The Black & Black suction aspirator is substantially equivalent in function and intended use to the Byron PSI-TEC (K981215). Both the Byron PSI-TEC and the Black & Black Vitruvian Aspirator have Dual vacuum motors, a Vacuum gage read-out, metal housing, 4 casters, an IV pole, fitting for suction tubing, and a 0.3 micron filter. Both devices are used for aesthetic body contouring.

The steps of operation of the Vitruvian Aspirator can be found in the IFU.

9. **Performance Testing**

The device complies with the following standards:

<b>Tested/Evaluated Standard</b>	<b>Results</b>
IEC/EN 60601-1-2:2007/AC:2010 Clause 4.1	Complies
IEC/EN 60601-1-2:2007/AC:2010 Clause 5	Complies
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)	All Requirements/Tests either Passed or were N/A
IEC 60601-1-6:2010 (Third Edition)	All Requirements/Tests either Passed or were N/A
IEC 62366: 2007 (First Edition)	All Principles Evaluated either Passed or were N/A

Performance Testing Performed at Manufacturing Facility:

- Vitruvian Ultimate Aspirator Vacuum Display Calibration – All test results are within acceptable criteria range

10. **Substantial Equivalence Conclusion:**

Based on the information contained in this submission, it is concluded that the Vitruvian Ultimate Aspirator is substantially equivalent in function and intended use to the identified predicate device, the Byron PSI-TEC Aspirator, K981215.