September 13, 2024

Black & Black Surgical, Inc.
Cynthia Rees
Regulatory Manager
5175 South Royal Atlanta Dr.
Tucker, Georgia 30084

Re: K240188
Trade/Device Name: Vitruvian Liposaber™
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: QPB,
Dated: January 23, 2024
Received: January 24, 2024

Dear Cynthia Rees:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alicia Hemphill -S

Digitally signed by Alicia Hemphill -S
Date: 2024.09.13 18:03:30 -05'00'

Alicia Hemphill, MS
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240188

Device Name
Vitruvian LiposaberTM

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.

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510(k) Summary

In accordance with SMDA 1990, 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Vitruvian Liposaber™ is provided below.

1. **Submitter Information:**
   Prepared: 12/08/2023

   Est. Reg. #: 3006142527

   Norman M. Black, CEO, normanblack@blackandblacksurgical.com
   Black & Black Surgical, Inc.
   5175 South Royal Atlanta Dr.
   Tucker, GA 30084
   770-414-4880 T / 770-414-4879 F

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

2. **Device Identification:**

   Trade/Proprietary Name: Vitruvian Liposaber™
   Common/Usual Name: Suction Lipoplasty System
   Classification Name: System, Suction, Lipoplasty for Removal
   Regulation Number: 878.5040
   Product Code: QPB
   Device Class: Class II
   Classification Panel: General & Plastic Surgery

3. **Substantial Equivalence:**
   The Vitruvian Liposaber™ is substantially equivalent to the devices listed below in terms of use, design, operating principles, materials, and performance.

   MicroAire PAL System, K212024

4. **Device Description:**

   The Vitruvian Liposaber™ consists of a control unit with an interconnecting cable to power and control a handpiece. The handpiece employs a motor intended to imitate the surgeons repetitive back and forth motions used during the liposuction procedure. The handpiece holds the cannula and the vacuum tubing. The handpiece is controlled by the user through the interaction with the control unit. The control unit controls the speed of the motor in the handpiece which provides the reciprocating motion of the cannula. The speed of the motor is variable between 3000 and 5000 RPM. The nominal speed is 4000 which can be adjusted using the controls on the handpiece between 3000 and 4000 RPM. Adjustments higher than 4000 must be performed through the user interface on the control unit.

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

Control Unit: Turns device power on and off and is attached to handpiece with a 10 ft cable. The Control Unit includes an interface to allow the user to change the motor speed between 3000 to 5000 RPM at 100 RPM steps and start and stop the cannula motion. The Control Unit is outside the sterile field.

- **Power Operation**: 100-240VAC, 50-60Hz, 0.1-0.2A
- **Handpiece**: Anodized aluminum body with stainless steel shaft to drive the cannula in a reciprocating motion. The handpiece is a reusable sterile component. The handpiece includes a user interface to allow the user to control the speed between 3000 – 4000 RPM and start and stop the canula motion.
- **Display**: LED
- **Connecting Cable**: Connects handpiece to control unit.
- **Power Cord**: Hospital Grade IEC 60320
- **Motor**: DC

5. **Indications for Use:** Aesthetic Body Contouring

6. **Comparison to Predicate**

Control Unit Comparison Chart

Item	Predicate Device	Subject Device	Similarity
Device name	MicroAire PAL System	Vitruvian Liposaber	N/A
Device Manufacturer	MicroAire Surgical Instruments, LLC	Black & Black Surgical, Inc.	N/A
510(k) Reference	K212024	K240188	N/A
Image			N/A
FDA Product Code	QPB	QPB	Same
FDA Classification	System, Suction, Lipoplasty for Removal	System, Suction, Lipoplasty for Removal	Same
FDA Regulation #	21 CFR 878.5040 Class II	21 CFR 878.5040 Class II	Same
Indication for Use / Intended Use	For Aesthetic body contouring.	Aesthetic body contouring.	Same
Device Overview			
User	Only trained and experienced healthcare providers/professionals should use this medical equipment.	Should only be handled and operated by healthcare professionals completely familiar with use of the device.	Same
Mechanism of Action	MicroAire power assisted liposuction is an electronic control system designed to reciprocate a cannula in lipoplasty applications.	The Vitruvian Liposaber is an electronic control system designed to reciprocate a cannula in lipoplasty applications.	Same

Item	Predicate Device	Subject Device	Similarity
Display	The color touch screen display provides an intuitive graphical user interface that allows users to view system status and set parameters with a touch of the screen.	LED Display of the speed of the motor in stroke per minute (RPM)	Similar
Speed Control	Touch screen Handpiece	Control Unit Buttons Handpiece	Similar
Physical Characteristics			
Dimensions	304.8 mm x 355.6 mm x 152.4 mm	168 mm x 125 mm x 185 mm	Different – Dimensional physical characteristics do not affect the safety and effectiveness of the device.
Weight	6.35 kg	1.7 kg	Different - Weight variance related to physical characteristics does not affect the safety and effectiveness of the device.
Display	Color Touchscreen Display	LED Display	Similar
AC Powered	100 VAC – 240 VAC, 50/60 Hz	100-240 VAC, 50/60Hz	Same
Number of Attachable Devices	Two (2) Handpieces	One (1) Handpiece	Different – A single handpiece connects to the Vitruvian Liposaber System to perform liposuction procedures only. This difference does not affect Safety and effectiveness due to the mode of operation.
Safety and Performance Testing			
Electrical Safety Tests Passed	IEC/EN 60601-1-2:2014 IEC 60601-1:2005 IEC 60601-1-6:2013 IEC 62366: 2015	IEC60601-1-2:2014+A1:2020 AAMI ES 60601-1:2005 IEC 60601-1-6:2010 AMD1:2013 IEC 62366:2007 A1: 2014	Same
Performance	4000 – 5000 strokes/min.	3000 – 5000 strokes/min.	Different - This difference does not affect Safety and effectiveness due to the mode of operation. The device is intended to replace the same manual motions made by the physician during a liposuction procedure.
Reuse			
Cleaning/Disinfecting	Validated germicidal wipe down method in IFU	Mild non-abrasive cleaner wipe down in IFU	Similar
Operating Environment			
Temperature	15°C to +24°C	0 deg C to + 40 deg C	Similar

Item	Predicate Device	Subject Device	Similarity
Humidity	20%-60%	<80%	Similar
Handpiece Comparison			
Item	Predicate Device	Subject Device	Similarity
Device name	PAL-650 Handpiece and 5006-PAL Cable	Vitruvian Liposaber Handpiece and Cable	N/A
Device Manufacturer	MicroAire Surgical Instruments, LLC	Black & Black Surgical, Inc.	N/A
Device Overview			
Image			N/A
User	Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction Lipoplasty.	Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction Lipoplasty.	Same
Mechanism of Action	The PAL-650 is a powered surgical instrument that reciprocates a cannula used in liposuction procedures.	The Vitruvian Liposaber handpiece is a powered surgical instrument that reciprocates a cannula used in liposuction procedures.	Same
Technology Overview	The reciprocating output shaft of the handpiece drives the cannula through a stroke distance of 2.8 mm (±0.4 mm) at a rate of 4,000 to 5,000 strokes/minute.	The reciprocating output shaft of the handpiece drives the cannula through a stroke distance of 2.90 mm (+/- 0.3mm) at a rate of 3,000 to 5,000 strokes/minute.	Similar
Physical Characteristics			
Dimensions	25 mm x 38 mm x 250 mm (width x thickness x length) [45.5 mm x 250 mm ~ equivalent diameter x length envelope]	30 mm x 40 mm x 250 mm (WxHxD)	Similar
Weight	0.5 kg (Handpiece) 0.28 kg (Cable)	0.8 kg (Handpiece and Cable)	Similar
Power Source	Console, detachable cable.	Console, detachable cable.	Same
Performance			
Duty Cycle	Duty cycle of 2 hours continuous use/ 2 hours.	Continuous	Different – non-clinical performance test demonstrates ability to perform continuously. Difference does not raise new issues of safety and performance.

Item	Predicate Device	Subject Device	Similarity
Patient Contacting Surface Temperature during Operation	<41°C	<41°C	Same
Reuse			
Cleaning	Manual Automated	Manual	Similar
Sterilization	Handpiece and cable are Autoclavable by end user, steam sterilization	Handpiece and cable are Autoclavable by end user, steam sterilization	Same

7. Non-Clinical Performance Data

To demonstrate substantial equivalence of the Vitruvian Liposaber System to the predicate device, Black & Black Surgical completed the following non-clinical tests. The results confirm the design inputs and performance specifications for the device are met. The Vitruvian Liposaber System was tested according to the internal design requirements, national standards, and international standards referenced below, supporting that the device is substantial equivalence to the predicate device.

- Biological evaluation per ISO 10993 – 1: The Vitruvian Liposaber instrument cable was considered biocompatible for the intended use.
- Electrical safety testing per IEC 60601-1 – the Vitruvian Liposaber System was found to comply with the requirements of the electrical safety standard.
- Electromagnetic Compatibility testing per IEC 60601-1-2: The Vitruvian Liposaber System demonstrated compliance to complied with the requirements of IEC 60601-1-2
- Software verification and validation per IEC 62304/FDA Software Guidance
- Functionality Verification Testing
    - Stroke Rate/RPM Display Calibration Validation – Pass
    - Stroke Distance Validation – Pass
    - Dynamic and Static Load Validation – Pass
    - Surface Temperature Validation – Pass
- Cleaning, Disinfection and Sterilization validation demonstrate the process produces a reusable sterile handpiece and cable with a SAL of 10^{-6}

8. Clinical Performance Data

No clinical testing was required to support the medical device as the indications for use are equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for years. The non- clinical testing details in this submission support the substantial equivalence of the device.

Statement of Substantial Equivalence

The Vitruvian Liposaber System, the subject device, has the same intended use and similar technological characteristics have been compared and contrasted with the predicate device. Non-clinical testing demonstrates the Vitruvian Liposaber System is substantially equivalent to the predicate device. Therefore, with the same intended use, similar technology and performance, the Vitruvian Liposaber System is substantially equivalent to the predicate device.