Norman M. Black III
Norman Black
CEO
2759 Hawthorne Drive Ne
Atlanta, Georgia 30345

June 9, 2021

Re: K113795
Trade/Device Name: Suction Lipolasty Accessories
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Norman Black:

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 7, 2012. 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 Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 7 2012

Black and Black Surgical, Incorporated
% Mr. Norman M. Black III
Chief Executive Officer
2759 Hawthorne Drive, Northeast
Atlanta, Georgia 30345

Re: K113795
Trade/Device Name: Liposuction Aspiration and Tumescent Infiltration Cannulae and Needles
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU, GEA
Dated: June 29, 2011
Received: July 05, 2011

Dear Mr. Black III:

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,

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

Enclosure

Indications for Use

510(k) Number: K113795

Device Name: Liposuction Aspiration and Tumescent Infiltration Cannulae and Needles

Indications for Use:

The aspiration and infusion cannulae and needles are indicated for aesthetic body contouring and general tissue aspiration.

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)

David Kwoka MM

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

510(k) Number K113795

BLACK & BLACK
SURGICAL

510(k) Summary in accordance with 21CFR 807.92. Assigned 510(k) number is K113795

AUG 7 2012

Traditional 510(k) Submission by:
Black & Black Surgical, Inc.
5238 Royal Woods Parkway
Suite 170
Tucker, GA 30084 USA
770-414-4880
Contact Person:
Norman M. Black III
CEO, Black & Black Surgical Inc.
770-414-1813

Date Prepared: June 29, 2012

Establishment Registration Number: 3006142527

Suction Lipoplasty System 21 CFR 878.5040 (05 Jan 1998)
Manual Surgical Instruments for General Use
21 CFR 878.4800 (1994)

Common Usual Name: Aspiration and infiltration Cannulae/Needles

Proprietary Name: Lipoplasty/Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles
(Cannulae and Needles)

Classification Name: Class II, 21 CFR 878.5040, Suction Lipoplasty System, Panel 79, MUU, General and Plastic Surgery

Predicate Device: **Suction Cannulae and Needles**
Manufacturer: Byron Medical, Inc.
510(k) Number: K981172
Substantially Equivalence Date: June 30, 1998

Device Description: Black and Black Surgical Cannulae and Needles are used to remove fluid, soft tissue, and exudates and infusion, utilizing a hollow stainless steel tube and multiple tips, handle and attachment connectors that are in reusable and disposable configuration. They are used during general, plastic, and reconstructive procedures.

Device Description Chart

Description*	Product Code	Length	Features	Packaging
Cannulae & Needles	B8- AAA— B8-ZZZ	Various	Straight	1 each

Black and Black Surgical Cannulae and Needles are manufactured of stainless steel tubes, with Aluminum Handles.

The patient contacting material in Black and Black Surgical Cannulae and Needles is stainless steel.

Indication for Use: The aspiration and infusion cannulae and needles indications are for aesthetic body contouring and general tissue aspiration.

Shared Technical Characteristics with Predicate Device:

The Black and Black Surgical Cannulae and Needles are substantially equivalent in function and intended use to the Byron Suction Cannulae and Needles (K981172). Both devices are used for aesthetic body contouring and general tissue aspiration by means of aspiration and infiltration which the FDA has found to be substantially equivalent to these devices in accordance with Section 878.5040 Suction Lipoplasty System.