Inex
Raymond Patel
Business Manager
Za La Gobette
60540 Puiseux Le Hauberger
Puiseux Le Hauberger, 60540
France

June 9, 2021

Re: K132353
Trade/Device Name: Suction Lipoplasty Accessories
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Raymond Patel:

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 July 30, 2014. 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

July 30, 2014

INEX
Mr. Raymond Patel
Business Manager
ZA LA GOBETTE
60540 Puiseux Le Hauberger
France

Re: K132353
Trade/Device Name: Cannulae and Needles
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU, GEA
Dated: June 27, 2014
Received: June 30, 2014

Dear Mr. Patel:

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″ (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 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 yours,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K132353

Device Name
Cannulae and Needles

Indications for Use *(Describe)*

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

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S
2014.07.30 13:50:56 -04'00'

INEX

K132353

510(k) Summary in accordance with 21CFR 807.92.

JUL 3 0 2014

Traditional 510(k) Submission by:

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France
laboinex@wanadoo.fr
Contact Person:
Raymond Patel
INEX
33(0)3.44.74.19.95

Date Prepared: July 29, 2014

Establishment Registration Number: 10042355

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: Black & Black Surgical, Inc. 510(k) Number: K113795 Substantially Equivalence Date: August 7, 2012

Device Description: INEX 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 disposable in configuration. They are used during general, plastic, and reconstructive procedures.

Device Description Chart

Description*	Product Code	Length	Features	Packaging
Cannulae & Needles	A — Z letters and 1 – 0 numbers.	Various	Straight and curved	1 each, 10/box & 20/box

INEX Cannulae and Needles are manufactured of stainless steel tubes, with Plastic Handles and Plastic Hubs.

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

Shared Technical Characteristics with Predicate Device:

The INEX Cannulae and Needles are substantially equivalent in function and intended use to the Black & Black Surgical Cannulae and Needles (K113795). Both devices are used for aesthetic body contouring and general tissue aspiration by means of aspiration and infiltration.

Biocompatibility testing per ISO-10993 demonstrated that the device is biocompatible.

Device	Design	Material	Function
INEX	Handle; Cannula tube; Tip	Plastic Handle; Stainless Steel Cannula Tube; Stainless Steel Tip with eyelets(holes)	The Handle is used to grip (hold) and to connect via tubing to the aspirator, wall suction or pump; the Cannula tube is used to provide length and strength; the Tip is used to provide suction and infiltration through eyelets (holes) in the tip.
Black & Black	Handle; Cannula tube; Tip	Aluminum Handle; Stainless Steel Cannula Tube; Stainless Steel Tip with eyelets(holes)	The Handle is used to grip (hold) and to connect via tubing to the aspirator, wall suction or pump; the Cannula tube is used to provide length and strength; the Tip is used to provide suction and infiltration through eyelets (holes) in the tip.
INEX	Luer Hub; Needle Tip	Polypropylene Luer hub; Stainless Steel Cannula Tube; Stainless Steel Tip with eyelets(holes)	The Luer hub is used to connect to an aluminum handle via tubing to the aspirator, wall suction, or pump; the Cannula tube is used to provide length and strength; the Tip is used to provide suction and infiltration through eyelets (holes) in the tip.

Summary

The only difference between the Black & Black Cannula and the INEX Cannula is the handle material. The Black and Black has an aluminum handle that can be autoclaved for multiple uses and the INEX Cannula has a plastic single use handle and is supplied sterile for single use. The function of the two handles is the same which is to allow the surgeon to grip and maneuver the cannula and to connect the sterile tubing to an aspirator, wall suction, or pump.

The only difference between the Black & Black needle and the INEX needle is the luer hub material. The Black and Black needle has a stainless steel luer hub that can be autoclaved for multiple uses and the INEX needle has a polypropylene single use luer hub and is supplied sterile for single use. The function of the two hubs is the same which is to allow the surgeon to join the needle to a handle and to connect the sterile tubing to an aspirator, wall suction, or pump.