Hk Surgical, Inc.
Sally Bowdon
General Manager
2620a Temple Heights Dr.
Oceanside, California 92675

June 8, 2021

Re: K032802
Trade/Device Name: Hk Liposuction Aspirator, Model Ap-III & Ap230-iii
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Sally Bowdon:

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 November 19, 2003. 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
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2003

Ms. Sally Bowman
General Manager
HK Surgical, Inc.
2620 Temple Heights Drive
Oceanside, California 92056

Re: K032802
Trade/Device Name: HK Liposuction Aspiration Pump
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: II
Product Code: MUU
Dated: September 3, 2003
Received: September 9, 2003

Dear Ms. Bowman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510K Number: K032802

Device Name: HK Liposuction Aspiration Pump

Indications For Use:

The HK Liposuction Aspiration Pump is for aesthetic body contouring.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032802

NOV 1 9 2003

510(k) Summary

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

'The assigned 510(k) number is K032002."

1. Submitter Information:

   HK Surgical, Inc.
   2620 Temple Heights Dr.
   Oceanside, CA 92056
   Ph: 800-909-0060 Fax: 949-369-9797

   Contact Person: Mrs. Sally Bowdon
   General Manager

2. Name of Device:
   Proprietary Name: HK Liposuction Aspirator III w/tubing
   Common Name: Aspirator Pump, Liposuction Aspirator, Powered Suction Pump

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

4. Product Code: MUU

5. Substantial Equivalence: The HK Aspiration Pump Model AP-III and AP230-III is believed to be substantially equivalent to the aspiration devices listed below in terms of intended use, design, operating principles, materials and performance.

   Byron Medical K980392
   Byron Medical K981215
   Kolster Methods K895761
   Wells Johnson K832274

6. Device Description: The HK Liposuction Aspiration Pump is a powered suction pump/ aspirator which uses an electrically (AC) driven vacuum pump generating a negative pressure for the removal of fat/adipose(Suction Lipoplasty), soft tissue, and general surgical waste.

7. Intended Use: Aesthetic Body Contouring

8. Signature of Applicant: Sally M. Bowdon
   Sally M. Bowdon, General Manager