

NOV 19 2003

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.”

The assigned 510(k) number is K032802.”

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



NOV 19 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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.

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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)

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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