



M28584

WARNING LETTER

AUG 11 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FACSIMILE
VIA FEDERAL EXPRESS

Jeffrey A. Klein, MD
HK Surgical, Inc.
30280 Rancho Viejo Road
San Juan Capistrano, California 92675-1561

Dear Doctor Klein:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed some promotional materials distributed by HK Surgical Incorporated (HK Surgical). The promotional materials list several products including HK Capistrano Microcannulas, HK Finesse Microcannulas and HK Vacuum Aspirator, and promotes all of them for use in the tumescent liposuction procedure. Microcannulas and aspirators are devices as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The intended use of the microcannulas that were cleared in HK Surgical's 510(k) premarket notification submissions designated 901717 and 901718 was as follows. The cannulas were designed to be passed into a surgically created body cavity for removal of fluids and tissues by suction.

In the May 24, 1990, clearance letter from the agency to you regarding the two microcannulas, the agency specifically stated that "[a]ny direct or indirect promotion of [these devices] for suction lipectomy would first require that a PMA be approved or the device[s] reclassified." Notwithstanding this specific prohibition, the agency has reviewed several items that promote HK Surgical devices for use in the tumescent liposuction procedure.

The promotional material reviewed by the agency includes a brochure entitled "Klein Tumescent Liposuction 3 Day Course for Surgeons." The inside panel of the brochure is entitled "New Products for Tumescent Technique from HK Surgical, Inc." The brochure informs the reader that "HK Surgical, Inc. will now be the exclusive source for all the tumescent technique equipment designed and developed by Jeffrey Klein, MD." It further states that "HK Surgical specializes in scientific designs for (1) products that optimize recovery and comfort after tumescent technique, (2) equipment for optimal tumescent infiltration, (3) patented microcannulas designed for optimal efficiency, and (4) the most quiet, cost effective, and efficient aspirators."

The "Klein Tumescent Liposuction 3 Day Course for Surgeons" which HK Surgical sponsors, is an impermissible promotion as it promotes the use of the HK Capistrano and Finesse Microcannulas and the HK Vacuum Aspirator in performing the tumescent

liposuction procedure. The HK surgical equipment is described as being specifically designed for the tumescent liposuction technique. The brochure describes the HK Vacuum Aspirator as an “efficient aspirator ...specifically designed for the tumescent technique...” The HK Capistrano Microcannulas are described as being “designed specifically for Tumescent Technique...” As stated previously, these devices were not cleared for use in liposuction procedures.

The agency has also reviewed your Internet site, www.hksurgical.com. The Internet site also contains the impermissible promotion of your products for use in the tumescent liposuction procedure. HK Surgical’s “Home Page” contains the following statement, “HK Surgical is a corporation that manufactures and markets equipment to facilitate tumescent liposuction procedures.”

In your March 15, 1999, correspondence to the agency, which you wrote in response to a March 3, 1999, letter from CDRH’s Office of Compliance, you indicate that the 510(k) clearance for the microcannulas was secured when HK Surgical was known as Jeff Klein Surgical, Inc. However, you fail to address the lack of a cleared 510(k) or approved PMA for the use of the microcannulas in the tumescent liposuction procedure.

In the same correspondence you indicate that the HK Vacuum Aspirator, which you market, is manufactured by KMI, Incorporated. The intended use of the aspirator that was cleared in KMI’s 510(k) submission, designated 895761, was for general surgical suction. It was declared substantially equivalent, in terms of proposed use, materials, design specifications, and principle of operation, to pre-enactment general suction aspirators. As established in 21 CFR 878.4780, a surgical pump/aspirator is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient’s airway or respiratory support system. The device may be used during surgery in the operating room or at the patient’s bedside. The device may include a microbial filter.

In your correspondence, you indicate that KMI, Inc. has the appropriate 510(k) on file. However, a search of FDA’s database reveals no such 510(k) cleared for use during liposuction procedures. In the October 18, 1989, clearance letter to KMI regarding the aspirator, the agency stated that “[a]ny direct or indirect promotion of this device for suction lipectomy would first require that a PMA be approved or the device reclassified.”

The claims for tumescent liposuction procedures have misbranded and adulterated, within the meanings of sections 502(o) and 501(f)(1)(B), respectively, of the Act, the HK Capistrano and Finesse Microcannulas and the HK Vacuum Aspirator. Each of the products is misbranded because a notice or other information respecting the device was not provided to the FDA as required by section 510(k) and none of them has been found to be substantially equivalent to a predicate device for the uses claimed. The devices are adulterated because they are class III devices under section 513(f) and do not have approved applications for premarket approval in effect pursuant to section 515(a) or approved applications for investigational device exemptions under section 520(g).

FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" of a device refers to the objective intent of the persons legally responsible for the labeling of a device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims regarding tumescent liposuction procedures changes the intended use of the HK Surgical devices. Pursuant to section 510(k) of the Act and as provided in 21 CFR 807.81(a)(3)(ii), claims that constitute a major change in the cleared intended use of a device require the submission of premarket notification to FDA. We have been advised by CDRH's Office of Device Evaluation that devices used for liposuction are now class II devices and subject to the agency's premarket notification regulations.

This letter is not intended to be an all-inclusive list of deficiencies associated with the mircocannulae and aspirator. The specific violations in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

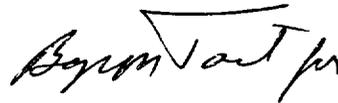
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunctions and/or civil penalties.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address misleading information currently in the marketplace and actions to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Terri Garvin, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Los Angeles District Office (HFR-PA240), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92715.

Sincerely,



Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health