



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
209B Gaither Road  
Rockville MD 20850

APR 16 1997

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

Mr. George Kempself  
President  
Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 33773-4908

Dear Mr. Kempself:

The Food and Drug Administration (FDA) has reviewed some promotional material and catalog ordering information referring to the "Linvatec Liposhaver Blades" and the "Liposhaver ." The object to which these names refer is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act) because it is used to diagnose or treat a medical condition or to affect the structure or function of the body.

The blades that you have described in these materials are used in conjunction with the Apex Universal Drive for ENT, which was cleared by FDA's Center for Devices and Radiological Health pursuant to 510(k) numbers K944476 and K964548, which Linvatec submitted in accordance with section 510(k) of the Act. The intended use for the Apex device is as "the drive system for various handpieces and blades used for shaving of soft tissue and bone during otolaryngological and reconstructive surgery." Your intended use statement also says that the handpieces are used to drive blades, burrs, and routers in performing otolaryngological and reconstructive surgery and that the blades, burrs and routers are used for shaving of soft tissue and bone during otolaryngological and reconstructive surgery.

The intended uses for the blade are set forth in the provisions of section 21 CFR 874.4140. That section describes ear, nose and throat burs as follows, "(a) *Identification.* An ear, nose and throat bur is a device consisting of an interchangeable drill bit intended for use in an ear, nose and throat electric or pneumatic surgical drill (§ 874.4250) for incising or removing bone in the ear, nose or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

**(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.”**

**The uses described in the CFR are the only uses that allow the device to remain exempt from the premarket notification requirements.**

**The promotional materials distributed at the 100<sup>th</sup> annual meeting of the American Academy of Otolaryngology at the Washington, DC Convention Center from September 29-October 2, 1996 promote the device for head and neck adipose tissue resection and compare the use of Linvatec’s device with conventional liposuction. The catalog ordering information refers to the “Liposhaver” blade, which implies the use of the device for fat removal. Neither the clearance for the Apex system nor the exemption for the blade includes liposuction or the resection or removal of adipose tissue.**

**In legal terms, these materials have misbranded both the blade and the Apex drive system within the meaning of section 502(o) of the Act and adulterated them under section 501(f)(1)(B). The products are misbranded because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed for the particular uses for which you are advertising the devices. They are adulterated in that you did not obtain premarket approval based on information developed by you that shows your device is safe and effective.**

**FDA’s regulations at 21 CFR 801.4 provide that the term “intended uses” refers to the objective intent of the persons legally responsible for the labeling of the 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 liposuction impermissibly changes the intended use of the device. Pursuant to section 510(k) and as explained in 21 CFR 807.81(a)(3)(ii), claims that state or imply that the device can be used for liposuction require the submission to FDA of premarket notification.**

**There are several news articles, including a Roanoke Times & World News article dated March 16, 1996 and an October 19, 1995 Reuters news wire article, that describe the procedure for the removal of fat practiced by Dr. Charles Gross and associate that procedure with the word “liposhaver” and the name “Linvatec.” While we have not located any more recent articles and while these articles do not attribute to Linvatec officials or employees any statements regarding the device, we advise you that, for future reference, any statement that is attributable to anyone at Linvatec that promotes the device marketed by Linvatec for liposuction or for the removal of fat or for any use that is not within the cleared intended use for the device, as provided above, will further misbrand and adulterate the device.**

**This letter is not intended to be an all-inclusive list of deficiencies associated with the Linvatec blades. It is your responsibility to ensure adherence to each requirement of the Act and the Federal regulations. 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 deviations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, and assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days of your receipt of this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), 2098 Gaither Road, Rockville, Maryland 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and the related issues of how you promote and advertise the device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at (800) 638-2041 or on the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter, you may contact Deborah Wolf at (301) 594-4639.

A copy of this letter is being sent to FDA's Florida District Office. Please send a copy of your response to the District Director, Florida District Office, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809.

Sincerely yours,



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