



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 13 1997

WARNING LETTER**VIA FEDERAL EXPRESS**

Mr. Shimon Eckhouse
President
Luxar Corporation
11911 North Creek Parkway South
Bothell, Washington 98011-8809

Re: Silhouette™ Liponic
Sculpting System™

Dear Mr. Eckhouse:

The Food and Drug Administration (FDA) has reviewed the promotional materials submitted by Phillip Burwell, Luxar Clinical and Regulatory Affairs Manager, on July 26, 1997, in response to our letter dated July 9, 1997, for Luxar Corporation's Silhouette™ Liponic Sculpting System™ (Silhouette™). The Silhouette™ is manufactured by Luxar Corporation (Luxar), Division of and is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

A therapeutic massager is defined in the regulations at 21 CFR 890.5660 as an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains. FDA has also allowed manufacturers to use the claims "temporarily increases local blood circulation," and, "relaxes muscles locally." Under a reclassification order of January, 1996, therapeutic massagers, when limited to these indications, were exempt from the premarket notification requirements.

However, Luxar's promotional materials including brochures, pamphlets, flyers, Silhouette™ Operator Manual, videotape titled, Introducing the Luxar Silhouette™, and your web site at the Internet address: <http://www.luxar.com>, make claims that the Silhouette™ can reduce the appearance of cellulite while improving body shape and skin tone, and implies benefits to patients who have undergone liposuction. The following representative claims are not meant to be all-inclusive:

- "Introducing Silhouette™. The non-invasive method of improving the appearance of both cellulite and patient body shape."

Brochure titled, Desperate Measures...Measured Results;

- "The Silhouette™ uses a non-invasive technology called Liponic Sculpting™ which acts on the hypodermal layer of the skin and can reduce the appearance of cellulite,

plus enhance overall skin tone making it look and feel healthier;"

- "Liponic Sculpting provides an effective alternative for an improved body image;"
- "Liponic Sculpting is applied to the hypodermic layer of the skin where the cellulite condition resides. Liponic sculpting affords a convenient, practical and effective non-surgical approach for reducing the appearance of cellulite. The treatment also has been shown to enhance skin tone and body shape;"

Brochure P/N 01503-01 Rev. A titled, Silhouette™. The brightest minds in aesthetic medicine;™

- "Silhouette™'s Liponic Sculpting™ also offers a new modality for patients who have undergone liposuction to improve skin tone and texture imperfections;"

From Light News, Vol. 3, No. 3. A Publication of ESC Corporation, parent company of Luxar.

Additionally, Luxar's brochure dated 1997 contains pictorial representations of patient profiles and shows differences in body shape both before and after treatment with the Silhouette™. Captions next to several photographs state in part, "Significant change in the appearance of cellulite, skin tone, and texture."

Although we agree with Luxar's plans to represent the Silhouette™ as a therapeutic massager and to delete all references to body sculpting or shaping as discussed in our August 6, 1997 telephone conversation with Mr. Burwell, we believe use of the words such as "Liponic Sculpting" in the trade name are misleading because they imply the device has uses other than therapeutic massage.

The agency has determined that a therapeutic massager with any claim related to cellulite reduction continues to meet the definition of a device within the meaning of section 201(h) of the Act. Before Luxar can make the claim that the Silhouette™ "may lead to a temporary reduction in the appearance of cellulite," or any similar wording, Luxar must either demonstrate that the claim falls within the exempted status of the device, file a new premarket notification for the claim, or petition the agency to include the claim as part of the exemption for therapeutic massagers. A copy of FDA's guidance document on how to file a 510(k) is enclosed for your reference.

If Luxar elects to provide the agency with data to show that the claim falls within the exempted status of a therapeutic massager, Luxar should demonstrate that any or all of the above referenced indications for therapeutic massagers result in a temporary reduction in the appearance of cellulite.

Luxar may at this time only promote its Silhouette™ device as a therapeutic massager. Continued promotion or sale of the Silhouette™ for reduction in the appearance of cellulite, "Liponic Sculpting," body contouring, skin toning, weight loss etc., may result in the Silhouette™ being misbranded and adulterated.

In legal terms, the Silhouette™ is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Silhouette™ is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device were not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Silhouette™. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

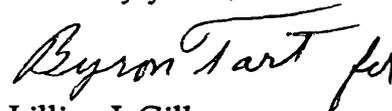
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Seattle District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Seattle District Office, 22201 23rd Drive S.E., P.O. Box 3012, Bothell, Washington 98401-3012.

Sincerely yours,



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

Enclosure