DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2003

Richard A. Stolworthy
2303 Hurstbourne Village Drive
Suite 100
Louisville, KY 40299

Re: Docket No.02P-0437

Dear Mr. Stolworthy:

This responds to your citizen petition dated October 4, 2002, and filed by the Food and Drug Administration (FDA) on October 8, 2002.

Petition

Your petition requests that FDA better protect patients and consumers in the United States by amending the FDA 510(k) policy to include disclosure and labeling requirements, better evidence of the safety and efficacy of medical devices and products, and accountability for claims made by 510(k) submitters.

Background

As background, on May 28, 1976, the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (the Act) were enacted. This legislation allowed the FDA to perform a premarket review of new devices before marketing in the United States. If FDA determines that devices that required premarket notification under section 510(k) of the Act are substantially equivalent to those which were on the market prior to May 28, 1976, the 510(k) applicant may commercially distribute the device in the United States.

In 1986, FDA issued a guidance document entitled, "Premarket Notification Review Program" (copy enclosed). This document was FDA's first guidance on premarket notification (510(k)) review and the meaning of the term "substantial equivalence." In 1990, the Safe Medical Devices Act amended the Act and codified the agency's interpretation of "substantial equivalence." Basically, for a device to be determined to be substantially equivalent, there must be a legally marketed device for comparison. The term "legally marketed device," for purposes of substantial equivalence, is found in Title 21 of the Code of Federal Regulations (CFR) 807.92(a)(3). This section states that a legally marketed device "... is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket

02P-0437 LET 1

notification process." The process of 510(k) review is one of comparing the new device to the predicate device, first in intended use, next in technology, and lastly in assuring that it performs at least as safely and effectively as the predicate device. The degree of similarity between the device under review and the predicate will determine whether we review specifications, bench data, animal data and/or clinical data. If we determine from our review that the new device is at least as safe and effective as the predicate device, we will find the device to be substantially equivalent and allow marketing in the United States.

In your petition, you state your concerns with the Epilight Hair Removal System and our review of that device. In response to your concerns, you should know that we do require 510(k)s of all devices of this type for this indication for use. All initial devices for hair removal, whether laser or intense pulsed light systems, undergo the same type review. Applicants must provide clinical data on safety and effectiveness for all new wavelengths or combination of wavelengths.

Applicants must provide clinical data that includes follow-up of the patient at 0-7 days and at 1 and 3 months. Persistence of adverse effects, such as burns or blistering, or the appearance of new adverse effects such as hyper- or hypo- pigmentation, could prevent clearance or result in requests for additional information. FDA evaluates effectiveness based on percent of hair loss at 3 months, and expects hair reduction of at least 30% from baseline at 3 months. Also, to make a general claim for hair removal, the applicant must demonstrate that a majority of subjects show this effect in a variety of anatomical locations, including the face. If not, the manufacturer may only label the device for indications specifically limited to the sites supported by the data .

Specific Actions Requested

The following is a summary of your requests and FDA's responses to those requests

1. FDA should require labeling in all marketing/promotional materials that promote products and devices cleared under 510(k), informing consumers and patients that FDA approval is based solely on the claims and opinions of the applicant, and that the FDA neither sees nor tests the device or product, nor confirms or endorses the manufacturer's claims.

Section 807.97 (21 CFR 807.97), "Misbranding by reference to premarket notification," states, "Any representation that creates an impression of official approval of a device because of complying with section 510(k) of the Act would be misleading and constitutes misbranding." As outlined above, devices that require review of a 510(k) before marketing may not be marketed until FDA has found the device to be substantially equivalent. This determination is not based solely on the claims and opinions of the applicant, but rather on the review of necessary information by the FDA.

2. FDA should require that all verbal or printed references to the FDA approval of a medical device or product by the manufacturer or its representatives must be accompanied by disclosure of the 510(k) guidelines and limitations as stated above.

As stated above, a device that has gone to market through the 510(k) process can not have labeling that states the device is FDA approved. We do post 510(k) substantial equivalence determinations on our website as well as numerous documents explaining the 510(k) requirements and review process.

3. FDA should revise it policies to require that: (a) All 510(k) applications or summaries include copies of all test studies or other reports leading to the conclusions and/or opinions stated in the summary or application; (b) All studies and/or reports included in the applications be signed and certified by the authors and the 510(k) applicant(s); and (c) All printed, verbal, or implied financial relationships or agreements or prospective financial agreements between the 510(k) applicant and any individual or entity involved in the test studies be disclosed in the application.

Section 807.87(k) (21 CFR 807.87(k)) requires that a 510(k) applicant include in the 510(k) a signed statement that all information included in the 510(k) is truthful and accurate to the best of his or her knowledge and that no material fact has been omitted. Section 807.87(i) (21 CFR 807.87(i)) requires that an applicant include within a 510(k) a financial certification or disclosure statement or both as required by 21 CFR Part 54.

4. FDA should investigate ESC Medical Systems, now operating as Lumenis ("LUME"), the Epilight 510(k) application submitted in 1996 and all tests and studies relating to the application, as well as other 510(k) applications submitted thereafter by ESC and Lumenis.

In your last request, you state that the FDA should investigate the premarket notification for the Epilight Laser System and other 510(k)s that were subsequently submitted by ESC Medical Systems and its successor corporate entities. Absent clear evidence that any premarket information submitted to the agency was unfounded, misstated, or untrue, FDA maintains a "level playing field" for all manufacturers of medical devices through postmarket programs.

A manufacturer of this type of device would be responsible for compliance with a number of postmarket programs which help ensure a device's safety and effectiveness. These postmarket programs include the following:

1) Manufacturing operations and design controls, under the Quality System regulations (21 CFR Part 820);
2) Reports by an end user, e.g., a clinician or hospital, to the manufacturer, and in some circumstances to FDA, of certain adverse events associated with the device, under the Medical Device Reporting program (21 CFR Part 803);
3) Reports to FDA of a corrective action or removal of a device or group of devices, either temporarily or permanently, when a firm recognizes a risk to health is associated with the device and there is a regulatory violation, as required under the Reports of Corrections and Removals program (21 CFR Part 806); and
4) Finally, manufacturers remain subject to onsite inspections to determine their compliance with applicable regulations and provisions in the Act.

The agency routinely considers requests such as yours for investigations and, in each situation the agency considers a number of factors to determine appropriate follow-up. These include:

- The agency's assessment of any related risk to health;
- The agency's review and evaluation of existing information and reports, such as those generated by postmarket activities;
- The indications for use, whether prescription or over-the-counter, that may relate to a broader public health concern; and
- The availability of our resources.

In any case, FDA does not disclose the status of any investigations, such as the one you suggest, unless and until we complete the investigation.

I believe that this response has answered your concerns with the 510(k) program and specifically hair removal devices. If you have any questions regarding this letter, please contact Joseph M. Sheehan of our Regulations Staff at 301-827-2974.

Sincerely yours,

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health

Enclosure