

Executive Summary Dermal Filler Devices

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FDA General and Plastic Surgery Panel:

Energy Delivery Devices for Dermatology and Aesthetic Indications

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I. Introduction

FDA is responsible for regulating dermatology devices that impart energy to the body. These devices deliver a wide variety of energy types and energy levels and cover a broad spectrum of device types from Low level Light Therapy, to mechanical massagers, to powerful CO₂ lasers that remove the stratum corneum.

Presently, almost all of the devices that fall within this area are cleared as Class II devices for prescription use only. Class II devices receive FDA marketing clearance through the 510(k) premarket notification process in which the manufacturer is required to demonstrate that the subject device is as safe and effective as a legally marketed device of the same type.

The use of these devices has changed over the years. Initially, only licensed physicians performed procedures such as wrinkle treatment, removal of lentigines, treatment of spider veins, skin tag removal, etc. As the devices became “safer”, their use moved from the physician’s office and clinic into beauty salons and health spas. Some of these salons and spas are established only to perform these dermatologic procedures. In addition, the user is now not only the licensed physician, but can, and often is, a cosmetologist, aestheticians, or some other ancillary technician.

The main issue before you today is the methodology to be used for evaluation of energy deposition devices that deposit relatively low amounts of energy and produce a relatively small tissue effects. In general, the comparative safety of these low energy devices is simple to evaluate. We are seeking your recommendations on evaluation of the effectiveness of these low energy device treatments as compared to legally marketed devices of the same type.

II. Types of Energy Delivered by Dermatology Devices

FDA has cleared hundreds of energy delivering devices for dermatological use. The types of energy delivered to the body are listed in Figure 1. The effects of these various energy types range from intense heat or cold that can produce significant tissue damage to very slight energy deposition which results in subtle tissue effects that are difficult to quantify objectively. In addition, many companies are combining these devices into multi-device platforms that are designed to use the different energies simultaneously or sequentially with each other.

Figure 1: Types of Energy Delivered

Light Based Systems:

- Lasers,
- LEDs
- Intense Pulsed Lights

Ultrasound including Focused Ultrasound

Radio Frequency

TENS

Microwave

Cryo-Therapy

Mechanical Massagers

Combinations of the Above

III. Legally Marketed Indications for Energy Delivery Dermatology Devices

Figure 2 presents a list of the different indications for which the energy delivering dermatology devices are currently being marketed.

Figure 2: Dermatologic and/or Aesthetic Indications for which devices are legally marketed.

Treatment of:

Wrinkles

Pigmented Lesions

Vascular Lesions

Acne Vulgaris

Treatment for:

Hair Removal

Hair Growth

Tattoo Removal

Temporary Reduction in the Appearance of Cellulite

The indications for use listed in Figure 2, except for the Temporary Appearance of Cellulite (a preamendments indication for a device), were all initially granted marketing clearance based on clinical trial data.

IV. Regulatory Issues

FDA's approach to the premarket review of dermatologic energy deposition devices is to determine whether they are "substantially equivalent" to predicate devices, i.e., as safe and effective as legally marketed devices of the same type.

For devices seeking to treat wrinkles, study endpoints were based on a validated wrinkle severity scale, the Fitzpatrick Wrinkle Severity Scale, and confirmatory histology. This scale is divided into two components. The first permits classification of wrinkle severity into mild, moderate, or severe scores. The second component subdivides these three scores into subsets based on a 1-9 scale that reflects elastotic damage. FDA encouraged the use of the 1-9 elastosis damage scale where the assessment is based on photographs scored by masked evaluators.

The other indications listed in Figure 2 were cleared based on evidence of changes to lesions or hair numbers or photographic evidence that pigmented and vascular lesions disappeared or became lighter. Photographic evidence was also used for indications related to tattoo treatment.

Except for mechanical massagers, which are class I exempt from 510(k) and have the "temporary reduction in the appearance of cellulite" indication, all other devices that have these aesthetic indications for use are Class II medical devices and the majority of these are prescription devices. At the time of their clearance for marketing, these devices were essentially used in doctor's offices, clinics, or hospitals.

Initially, dermatology energy deposition devices used high energy that caused significant and immediate tissue effects. For example, high power CO₂ lasers indicated for wrinkle treatment perform that treatment by removing the entire stratum corneum. Clinical trial data were used to demonstrate at least a 2 point improvement in the Fitzpatrick elastosis scale prior to clearance.

Today, many of the technologies under consideration use minimal energy deposition and create consistent minimal changes in the dermal tissue. For example, a biostimulation laser may produce < 100mW of output, create no thermal effect, and no visible dermal reaction. This energy level is similar to the 75 watt incandescent light bulb in your lamp at home. As these devices and their output energies become lower and safer, the risk these devices pose to the general public is also lowered.

The main issue before you today is the methodology to be used for evaluation of energy deposition devices that deposit relatively low amounts of energy and produce a relatively small tissue effect. In general, the comparative safety of these low energy devices is simple to evaluate. We are seeking your recommendations on evaluation of the effectiveness of these low energy device treatments as compared to legally marketed devices of the same type.

V. New Indications for Use

An ever increasing number of the dermatologic energy deposition devices is being promoted and marketed through web sites for indications that may or may not be clearly medical in nature, such as “improves the appearance of the face” or “makes you look healthier”.

Attached is a copy of the type of information one can frequently find on web sites promoting a low level laser or light source for multiple indications for use most of which have never been evaluated by FDA. Similar types of promotional claims are often found in published literature such as the Aesthetic Buyers Guide which can be accessed at www.miinews.com. Other similar sites include the Skin and Aging magazine at www.skinandaging.com and the Aesthetic Dermatology News at www.adnmag.com. These types of internet sites frequently extoll the therapeutic benefit of various devices in written articles as well as in the accompanying promotional material.

Over time the use of these devices has moved out of doctors’ offices and clinics and into spa, beauty salons, and stand alone medical spa facilities. At the same time, use of many of these devices has shifted from physicians to use by cosmetologists and aestheticians especially as the energy outputs have become lower with apparent increases in safety. With this shift in use from physician offices to spas, the indications have also shifted with companies publishing studies/experiences or promoting their devices for indications such as those listed in Figure 3.

Figure 3: New Indications*

Body Contouring

Change in Thigh Size

Abdominal Tightening

Skin Tightening (Neck, Arms)

Fat Melting

Eye Brow Lift/Eye Lid Tightening

Lipolysis (Not Liposuction)

*By new indications, we mean indications for use that have recently been granted marketing permission and others that have been reported in the literature or on the Web and for which marketing applications are expected.

Validated or accepted measures of success do not yet exist for most of these indications. For many, such as body contouring, skin tightening and eyelid tightening, the amount of change

produced by the device is relatively small and does not lend itself easily to actual physical measurement. On the other hand, indications such as thigh size and eye brow lift may be measurable but the amount of change is still relatively small and it may not be clear what represents “clinically” meaningful change.

FDA’s efforts to understand the performance of treatments for which there are no accepted, validated and objective measurement tools/scales, have led to the development of measuring tools that ODE has accepted for specific measurements. For example, FDA has agreed to a thigh measurement method that involves measurements that are taken at the same location by the same individual in order to reduce variability. Similarly, ODE is aware of sponsors who have developed observational tools based on photographic training systems for such indications as eye brow lift. These systems involve the training of evaluators to recognize improvement in facial or body characteristics and the subsequent use of these photographic endpoints to evaluate photographs of study subjects. These methods have inherent limitations such as inter-evaluator variability and the limited within-evaluator reproducibility.