Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use

Document issued on: April 14, 2011

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Food and Drug Administration
Center for Devices and Radiological Health

General Surgery Devices Branch
Division of Surgical, Orthopedic and Restorative Devices
Office of Device Evaluation

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*. Comments may not be acted upon by the Agency until the document is next revised or updated.

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1. Introduction

This guidance document was developed as a special control guidance to support the classification of the low level laser system for aesthetic use into class II (special controls). The device is intended to apply low level laser energy to the body to achieve temporary changes in physical appearance. This guidance document is issued in conjunction with a Federal Register notice announcing the classification of the low level laser system for aesthetic use.

Following the effective date of the final rule, manufacturers of devices within this generic type of device will need to address the issues covered in the special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. These recommendations are in addition to the requirements that low level laser systems must also meet under 21 CFR 1040, Performance Standards for Light-Emitting Products.[1]

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the low level laser system for aesthetic use. Therefore, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the FD&C Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with the low level laser system for aesthetic use, including those identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

[1] These devices must comply with 21 CFR 1040.10, Laser products, and 21 CFR 1040.11, Specific purpose laser products.

This special control guidance document identifies the classification regulation and product code for the low level laser system for aesthetic use (refer to **Section 3. Scope**). Other sections of this guidance document list the risks to health FDA has identified and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these low level laser systems and lead to a timely 510(k) review. This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, the guidance, **Format for Traditional and Abbreviated 510(k)s**[2] and the section of CDRH's Device Advice, **Premarket Notification Submission 510(k)**.[3]

3. Scope

The scope of this document is limited to the following class II device (product code OLI) described below.

21 CFR 878.5400 Low Level Laser Systems for Aesthetic Use

Identification. A low level laser system for aesthetic use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Classification. Class II (special controls). The special controls are: The FDA guidance document entitled: "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use." See 21 CFR 878.1(e) for availability of this guidance document.

4. Device Description

We recommend you identify your device using the regulation and product code described in **Section 3. Scope** and include the following:

Device Components
We recommend you identify all components, system software, and accessories within the scope of the 510(k).

Photograph or Drawing of the Device
We recommend you provide a photograph or drawing of the device. We also recommend you provide a functional block diagram (including all accessories).

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[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

[3] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm

Comparison to the Predicate Device
We recommend you explain how your device and the predicate are similar, with respect to indications for use and technological characteristics.

5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the low level laser system for aesthetic use addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as also shown in the table below. You should also conduct a risk analysis before submitting your premarket notification to identify any other risks specific to your device. We recommend the premarket notification describe the risk analysis method and include the results. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or you have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	Recommended Mitigation Measures
Ocular Injury	Section 6. Bench Testing Section 7. Software Validation Section 8. Clinical Testing Section 12. Labeling
Electrical Shock	Section 11. Electrical and Mechanical Safety Performance Testing (IEC 60601-1) Section 12. Labeling
Unintended Cell Damage	Section 6. Bench Testing Section 7. Software Validation Section 8. Clinical Testing Section 9. Biocompatibility Section 10. Electromagnetic Compatibility (IEC 60601-1-2) Section 12. Labeling
Use Error	Section 12. Labeling

6. Bench Testing

We recommend that preclinical testing be performed to demonstrate that the low level laser system for aesthetic use meets all design specification and performance requirements. In regard to laser power and performance, laser power measurements should be conducted and should demonstrate that the laser output power, specifically that reaching the target site, is predictable. Testing should accurately characterize the output beam profile and establish that the laser energy is delivered and concentrated in the desired target location. Testing should demonstrate the accuracy of the method for targeting the region of interest and, if applicable, for monitoring the progress or result of treatment.

Testing should be performed to assess the probability of system failure, the means by which system failure can be mitigated, and the means by which system failure is apparent to the user. The overall system should be tested to ensure proper performance to design specifications and to assess the failure modes and probabilities. Bench testing may also be used to assess the likelihood that the conditions of use may affect system performance.

7. Software Validation

We recommend that you submit the information for software-controlled devices described in **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**.[4] The kind of information we recommend you submit is determined by the "level of concern," which is related to risks associated with software failure. The level of concern for a device may be minor, moderate, or major. FDA believes that the software used to operate a low level laser for aesthetic use presents a "moderate level of concern" as described in the Software Guidance because a failure or latent design flaw could directly result in minor injury to the patient or operator.

In addition, we recommend that the development of the control software follow IEC 60601-1-4: Medical electrical equipment – Part 1-4; "General Requirements for Safety; Collateral Standard: Programmable electrical medical devices" or equivalent methods.

8. Clinical Testing

FDA may recommend that you collect clinical data for a low level laser system for aesthetic use with any of the following:

- indications for use dissimilar from a legally marketed system of the same type;
- designs dissimilar from designs previously cleared under a premarket notification; or
- new technology, i.e., technology different from that used in legally marketed low level laser systems for aesthetic use.

FDA will consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. Also note that, as with any premarket notification, any new intended uses or technology differences that raise new types of safety or effectiveness questions may be grounds for finding your device not substantially equivalent (NSE).

If a clinical study is needed, we recommend that you evaluate the safety and effectiveness of the particular low level laser system for aesthetic use demonstrating its ability to achieve the desired aesthetic results in a significant portion of the target population when

[4] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf

used for the proposed indications for use and under the proposed conditions of use, including adequate direction for use and warnings against unsafe use that appear in the labeling. We suggest that you use any clinical studies that are conducted to confirm the safety of the device that was established through bench testing.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining a 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812.[6] In addition the sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

9. Biocompatibility

We recommend that you evaluate the biocompatibility of the device as described in the International Organization for Standardization (ISO) standard ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing for intermittent external contact with intact external body surfaces. If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing.

10. Electromagnetic Compatibility (EMC)

We recommend that you demonstrate the EMC of the device by performing EMC testing as described in the following FDA-recognized standard or equivalent method.

- IEC 60601-1-2 (Second Edition, 2001) Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic compatibility – Requirements and Tests

11. Electrical and Mechanical Safety Performance Testing

We recommend that you demonstrate the electrical and mechanical safety of the device by performing electrical and mechanical safety testing as described in the following FDA-recognized standard or equivalent method.

- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety

12. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing the labeling that satisfies the requirements of 21 CFR Part 801.[7]

Device User Manual
We recommend that you provide a user manual with the device. The user manual should include descriptions of:

- the device and all accessories
- how the device interconnects with other components or accessories
- all features, functions, output modalities, and specifications
- all user-accessible controls
- indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display output jack, etc.
- illustrations of the device and accessories
- summary of clinical testing

Directions for Use
As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Labeling must, however, include adequate information for practitioner use of the device, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions. (21 CFR 801.109(d)).

Indications for Use

The indication for use should give the specific indication for use for which the device is being granted marketing permission and include the statement that the device is a low level laser system for aesthetic use.

We recommend that the indications for use be included in the user manual.

Contraindications
We recommend that you advise users with open wounds or lesions, active implantables (e.g., pacemakers or defibrillators), or metallic implants not to use the device in these areas.

Storage Conditions
We recommend that storage conditions be included in the user manual.

Warnings
We recommend that you describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

The warning section should also include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved.

We believe a warning is appropriate when the device is commonly used for a disease or condition for which there is a lack of valid scientific evidence of effectiveness for that disease or condition and such usage is associated with a serious risk or hazard.

Precautions

The precaution section of labeling should include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device, for example:

- We recommend that this section indicate or emphasize any need for protective eye wear during use.
- We recommend that this section identify any laboratory tests or other evaluations that may be helpful in following the patient's response in identifying adverse reactions and, if appropriate, specify the frequency of such tests or evaluations before, during and after use of the device.
- We recommend that this section identify any precautions to help prevent electrical shock, such as any need for specific device placement, appropriate electrical wiring needs, reminders to periodically check device wiring and accessories for damage, and avoidance of use of the device in environments where electrical shock is possible.