

# **Guidance for Industry and FDA Staff**

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## **Dental Curing Lights - Premarket Notification [510(k)] Submissions**

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and  
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# Preface

## Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

## Additional Copies

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## **Dental Curing Lights - Premarket Notification [510(k)] Submissions**

*This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.*

### **1. Introduction**

FDA has developed this guidance document to assist industry in preparing premarket notification submissions for dental curing lights intended for polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod (21 CFR 872.6070).

### **2. The Least Burdensome Approach**

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

### **3. Background**

A manufacturer who intends to market a device of this generic type should conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in [21 CFR 807](#) Subpart E, and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also [21 CFR 807.81](#) and [807.87](#)).

This guidance document identifies the classification regulations and product codes for dental curing lights (refer to **Section 5. Scope**). In addition, other sections of this guidance document provide additional information to manufacturers on addressing risks related to these devices in premarket notifications (510[k]s).

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 and “**How to Prepare a 510(k) Submission**” on FDA Device Advice at <http://www.fda.gov/cdrh/devadvice/314.html>.

Under “**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**,” <http://www.fda.gov/cdrh/ode/parad510.html>, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a guidance document addressing that device. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

### **4. The Content and Format of an Abbreviated 510(k) Submission**

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 21 CFR 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

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### **Coversheet**

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

### **Proposed labeling**

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to **Section 11. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

### **Summary report**

FDA recommends that the summary report contain:

#### **Description of the device and its intended use**

We recommend that you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. (Please refer to **Section 6. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an “indications for use” enclosure.<sup>1</sup>

#### **Description of device design**

We recommend that you include a brief description of the device design requirements.

#### **Identification of the risk analysis method**

We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the specific device’s design and the results of this analysis. (Please refer to **Section 7. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

#### **Discussion of the device characteristics**

We recommend that you discuss the device characteristics that address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis.

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<sup>1</sup> Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

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### **Description of the performance aspects**

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 9–11** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.<sup>2</sup> (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

### **Reliance on standards**

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard.<sup>3</sup>

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations**.<sup>4</sup>

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(1), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

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<sup>2</sup> If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

<sup>3</sup> See **Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions)**, <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

<sup>4</sup> <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

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As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

In general, the discussion above applies to any 510(k). The following is a specific discussion of how you should apply this guidance document to a premarket notification submission for dental curing lights.

## **5. Scope**

This document applies to dental curing lights for photoactivation of resins and dental bleaching agents (class II, product procode **EBZ**) classified under the following regulation.

### **21 CFR 872.6070 Ultraviolet Activator for Polymerization**

An ultraviolet activator for polymerization is a device that produces ultraviolet radiation intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod.

The scope of this guidance includes devices that use light sources such as quartz-tungsten-halogen lamps, light-emitting diodes (LEDs), and xenon-plasma arcs, as well as laser energy sources.

The scope of this guidance does not include heat or light sources intended exclusively for tooth bleaching procedures. These are classified under 21 CFR 872.6475, Heat Source for Bleaching Teeth, product code EEG. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations of §872.9.

## **6. Device Description**

We recommend you identify your device by regulation number and product code identified in **Section 5. Scope** and include a description of:

- the principles of operation (i.e., the scientific principles behind how the device achieves its intended use)
- how you plan to market the device (and accessories, if any).

We recommend you provide information to show how the new device is both similar to and different from the legally marketed device. Side by side comparisons, whenever possible, are desirable; for example, using a tabular format as shown below. We also



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recommend that you describe how any differences may affect the comparative safety and effectiveness of your device.

**Table 1: Device and Predicate Comparison Table**

<b>Descriptive Information</b>	<b>Device</b>	<b>Predicate</b>
<b>Intended Use</b> - including specific indications		
<b>Device Design</b> – i.e., operational modes, light source, power source, and accessories		
<b>Composition of Materials</b> – including chemical composition of patient-contacting portions of the device		
<b>Technical Specifications</b> – including light intensity, peak wavelength, depth of cure		
<b>FDA-Recognized Standards</b> – list of any you have followed, e.g., electrical safety, fire safety, EMC, EMI, biocompatibility <sup>5</sup>		

## 7. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of dental curing light devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis to identify any other risks specific to your device, and submit the results of this analysis. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

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<sup>5</sup> For the list of FDA-Recognized Standards, see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**Table 2. Risks and Mitigation Measures**

<b>Identified Risk</b>	<b>Recommended Mitigation Measures</b>
Ineffective treatment	Section 8. Performance Specifications
Thermal or optical injury	Section 8. Performance Specifications
Electrical injury	Section 9. Electrical Safety and Electromagnetic Compatibility
Electromagnetic interference	Section 9. Electrical Safety and Electromagnetic Compatibility
Cross-contamination	Section 10. Infection Control Procedures
Improper use	Section 11. Labeling

## **8. Performance Specifications**

We recommend that you evaluate your dental curing light device using the following FDA-recognized standard or equivalent method: **American National Standard/American Dental Association (ANSI/ADA) Specification No. 48, Visible Light Curing Units, 2004.**

In addition, to demonstrate the equivalence of your dental curing light device to other legally marketed devices, we recommend that you describe:

- irradiance at a distance of 2 mm from the distal end of the light guide at maximum light output showing the maximum light intensity ( $\text{mW}/\text{cm}^2$ )
- spectral irradiance plot at a distance of 2 mm from the distal end of the light guide at maximum light output showing the peak wavelength (nm)
- light source type; i.e., halogen, LED, plasma arc, wattage
- power source; i.e., battery or main power supply
- curing modes and safety controls
- depth of cure (mm) on a representative resin sample.

If your dental curing light is controlled by computer software, we recommend you follow the recommendations of the FDA guidance documents below:

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- **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**<sup>6</sup>
- **General Principles of Software Validation.**<sup>7</sup>

We recommend you demonstrate that the use of your device does not present a thermal hazard to the patient. For example, you may wish to demonstrate that, for the longest prescribed curing times, patient contacting portions of the device do not present a thermal hazard.

We recommend you demonstrate that the use of your device does not present an optical radiation hazard to the patient for the maximum expected exposure time in any single area associated with the use of the device; for example, showing that for the longest exposure times, the optical radiation emissions from the device do not present hazards.

## **9. Electrical Safety and Electromagnetic Compatibility**

We recommend you demonstrate the electrical safety of your device by following both FDA-recognized standards below or equivalent methods:

- **American National Standard/American Dental Association (ANSI/ADA) Specification No. 48, Visible Light Curing Units, 2004**
- **IEC 60601-1:1988, Medical Electrical Equipment – Part 1: General requirements for safety.**

We recommend you demonstrate the electromagnetic compatibility (EMC) of your device by following the recommendations of the FDA-recognized standards below or equivalent methods:

- **American National Standard/American Dental Association (ANSI/ADA) Specification No. 48, Visible Light Curing Units, 2004.**
- **IEC 60601-1-2:1993, Medical Electrical Equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and test**

## **10. Infection Control Procedures**

Dental curing lights are generally provided to the user as nonsterile devices. Patient-contacting portions, such as the light tip, are intended to be disinfected or sterilized before each use. We recommend you describe the parameters for disinfection,

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<sup>6</sup> <http://www.fda.gov/cdrh/ode/guidance/337.html>

<sup>7</sup> <http://www.fda.gov/cdrh/comp/guidance/938.pdf>

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sterilization, or both, as appropriate for your device, and include the validated method, suitable chemical disinfectants for the device material type, and the cycle variables—time, temperature, pressure.

## **11. Labeling**

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Products using lasers must also comply with 21 CFR Sections 1040.10 and 1040.11 and labeled according to 21 CFR 1040.10(g).

The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.<sup>8</sup> We recommend labeling include:

- maximum light intensity
- peak wavelength
- types of curing systems compatible with your device
- warnings about optical radiation and thermal hazards.

We recommend that the labeling and instructions for use of your device follow the recommendations of the FDA guidance: **Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance.**<sup>9</sup> In particular, the instructions for reprocessing should include details for the user on:

- disassembly
- cleaning
- rinsing
- disinfection/sterilization
- drying
- reassembly of the device
- use of disposable sheathing for other portions of the device.

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<sup>8</sup> Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

<sup>9</sup> <http://www.fda.gov/cdrh/ode/198.pdf>