Contains Nonbinding Recommendations

Draft – Not for Implementation

Dental Curing Lights - Premarket Notification (510(k)) Submissions

---

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on July 12, 2024.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices/DHT1B: Division of Dental and ENT Devices at 301-796-5620.

When final, this guidance will supersede "Dental Curing Lights – Premarket Notification [510(k)] Submissions" issued March 27, 2006.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00016017 and complete title of the guidance in the request.

Contains Nonbinding Recommendations

Draft – Not for Implementation

Table of Contents

Dental Curing Lights - Premarket Notification (510(k)) Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance document provides recommendations for 510(k) submissions for dental curing lights. The devices in the scope of this guidance emit non-ionizing optical radiation intended to photopolymerize dental restorative resins. FDA is issuing this draft guidance to clarify and provide recommendations for premarket submissions for dental curing lights, as well as reference relevant consensus standards. The recommendations are intended to promote consistency and facilitate efficient review of these submissions.

This guidance, when final, will supersede the guidance "Dental Curing Lights – Premarket Notification [510(k)] Submissions" issued March 27, 2006. This document supplements other FDA documents regarding the specific content requirements of a premarket notification (510(k)) submission. You should also refer to 21 CFR 807.87 and FDA's guidance, "Electronic Submission Template for Medical Device 510(k) Submissions."

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database. If submitting a Declaration of Conformity to a recognized standard, we recommend you include the appropriate supporting documentation. For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

In general, FDA's guidance documents 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.

II. Scope

The scope of this document is limited to dental curing lights regulated under 21 CFR 872.6070 and with the product code listed in the table below:

Table 1: Applicable Product Code

Product Code	Product Code Name	Regulation Number
EBZ	Activator, Ultraviolet, for Polymerization	21 CFR 872.6070

The scope of this document does not include laser devices for polymerization such as those regulated under 21 CFR 878.4810 or under 21 CFR 872.6070 with the product code QNF and devices that use heat, light, or other energy sources exclusively for tooth whitening (bleaching) procedures. Devices intended exclusively for tooth bleaching are class I exempt regulated under 21 CFR 872.6475, with product code EEG.

III. Premarket Submission Recommendations

A. Device Description

We recommend that you identify your device by the applicable regulation number and product code indicated in Section II above and include the information described below.

As part of the device description, we recommend that you provide a complete description of all components, patient contacting materials, and features of the dental curing light devices, including the following information:

- Labeled images and/or illustrations of all components that comprise the device;
- Descriptions of any accessories and/or protective equipment that are packaged with the device, e.g., radiometer, filters, shields, light guides, protective filter glasses;
- Engineering drawings and/or schematics of the interior of the device, particularly the light assembly;
- Descriptions of the power source, battery type, capacity, and electrical characteristics (e.g., frequency, voltage);
- Descriptions of the light source, number and placement of light sources (particularly for LEDs), and wattage; and
- Descriptions of all operational modes and any controls, sensors, or alarms.

B. Predicate Comparison

For devices reviewed under the 510(k) process, manufacturers must compare their new device to a similar legally marketed predicate device to support its substantial equivalence (section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act); 21 CFR 807.87(f)). This comparison should provide information to show how your device is similar to and different from the predicate. Side by side comparisons, whenever possible, are desirable. See below for an example of how this information may be organized. This table is not intended to represent an exhaustive list of comparative parameters; ensure you provide all relevant device descriptive and performance characteristics.

Table 2: Sample predicate comparison table to outline differences and similarities between the subject and predicate devices.

Description	Subject Device	Predicate Device **(Kxxxxxx)**
Indications for use		
Operational modes		
Light source		
Power source		
Accessories		
Maximum light intensity (or irradiance) (mW/cm^2)		
Radiant power output (or radiant flux) (mW)		
Peak wavelength (nm)		
Radiant exposure output range (J/cm^2)		
Composition of patient-contacting portions of device		
Other relevant characteristics…		

C. Labeling

The premarket notification must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels and labeling, sufficient to describe the dental curing light, its intended use, and the directions for use must be provided.

As prescription devices, dental curing lights are exempt from the requirement to have adequate directions for lay use required under section 502(f)(1) of the FD&C Act as long as the conditions in 21 CFR 801.109 are met. For instance, to be so exempt, labeling that furnishes information for use of the prescription device must, among other things, contain adequate information for such use, including indications, effects, routes, methods, and frequency, and duration of administration and any relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended (21 CFR 801.109(d)).

We recommend that the instructions for use include the following information:

- Total radiant power output (or radiant flux) (mW) throughout the exposure cycle;
- Maximum light intensity (or irradiance) (mW/cm^2);
- Peak wavelength (nm);
- Radiant exposure (or optical radiation dose) output range (J/cm^2);
- Recommended distance (mm) and angle (degrees) of use from the tooth surface;
- Recommended curing time(s);
- Instructions for the use of disposable sleeves for non-patient contacting portions of the device, as applicable;
- Instructions for the use of protective equipment such as shields, filter glasses, etc., as applicable, in accordance with the currently FDA-recognized versions of ISO 12609-1 *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications -- Part 1*: *Specification for products* and ISO 12609-2 *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications -- Part 2: Guidance for use*;
- Instructions on how to periodically check the irradiance output;
- Warnings about thermal hazards; and
- Reuse information as described in FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." Specifically, we recommend that your instructions for reprocessing address disassembly, cleaning, disinfection/sterilization, and reassembly of the device.

D. Reprocessing

Significance: Many of the patient contacting components of dental curing lights are reused, and should be adequately cleaned, disinfected and sterilized between uses to minimize infections while preventing device degradation.

Recommendation: Instructions on how to reprocess a reusable device are critical to ensure that a device is appropriately prepared for its initial and subsequent uses. For recommendations regarding the development and validation of reprocessing instructions in your proposed device labeling, refer to FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

E. Biocompatibility

Significance: Dental curing lights contain patient-contacting materials, which, when used for their intended purpose, (i.e., contact type and duration), may induce a harmful biological response.

Recommendation: You should determine the biocompatibility of all patient-contacting materials present in your device. If your device is identical in chemical composition, manufacturing and processing methods to dental curing lights with a history of safe use, you may reference previous testing experience or the literature, if appropriate. For some device materials, it may be appropriate to provide a reference to either a recognized consensus standard, or to a Letter of Authorization (LOA) for a device Master File (MAF). You should refer to the following FDA webpage for additional information on using device MAFs: https://www.fda.gov/medical-devices/premarket-approval-pma/master-files.

If you are unable to identify a legally marketed predicate device with the same nature of contact and contact duration that uses the same materials and manufacturing process as used in your device, we recommend you conduct and provide a biocompatibility evaluation as described in ISO 7405 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* for the endpoints outlined below. Per FDA's guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'," when FDA-recognized consensus standards exist for a particular device type, the biocompatibility recommendations in the device-specific consensus standard should be used instead of the recommendations outlined in ISO 10993-1. The biocompatibility evaluation should explain the relationship between the identified biocompatibility risks, the information available to mitigate the identified risks, and any knowledge gaps that remain. You should then identify any biocompatibility testing or other evaluations that were conducted to mitigate any remaining risks. We recommend that you consider the recommendations in the guidance or the standard, which identifies the types of biocompatibility assessments that should be considered and recommendations regarding how to conduct related tests.

Per ISO 7405 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* or ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and Attachment A of FDA's guidance on ISO-10993-1, dental curing lights are surface devices for a limited contact duration.

The following endpoints should be addressed in your biocompatibility evaluation:

- cytotoxicity;
- sensitization; and
- irritation or intracutaneous reactivity.

F. Software

Significance: Device software function(s) in dental curing lights ensures control of the operation and output of the curing light. Adequate software testing provides assurance that the device functions as intended.

Recommendation: Refer to the FDA premarket device software functions guidance "Content of Premarket Submissions for Device Software Functions" for a discussion of the software information that you should provide in your submission. The premarket software guidance outlines the recommended information to be provided in a premarket submission that includes a device software function based on the "Documentation Level" associated with the device. We generally consider the device software function(s) for dental curing lights to need a "Basic" Documentation Level. However, new or unusual indications, applications, or technological characteristics may result in an Enhanced Documentation Level.

We recommend that you provide a full description of the device software function(s) supporting the operation of the subject device following this software guidance. This recommendation applies to original devices/systems as well as to any software changes made to already-marketed devices. Changes to software must be revalidated, reverified, and documented in accordance with Design Controls, 21 CFR 820.30(g)(i), and documented in the Design History File, 21 CFR 820.30(j).[1] Some software changes may warrant the submission of a new 510(k). For further information on this topic, refer to "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."

If the device includes off-the-shelf software, you should provide the additional information as recommended in the FDA guidances "Off-the-Shelf Software Use in Medical Devices" and "Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software," which provide additional information regarding medical devices utilizing off-the-shelf software.

If the device is a multiple function device product and includes software function(s) that are considered "other functions," as that term is used in the guidance "Multiple Function Device Product: Policy and Considerations," the recommendations described in the aforementioned guidance should also be considered when preparing the software documentation for a premarket submission.

[1] On February 2, 2024, FDA issued a final rule amending the device quality system (QS) regulation, 21 CFR part 820, to align more closely with international consensus standards for devices. FDA also made conforming amendments to 21 CFR part 4 (89 FR 7496). This final rule will take effect on February 2, 2026. Once in effect, this rule will amend the majority of the current requirements in part 820 and incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, in part 820. As stated in the final rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR part 820 in this guidance to be consistent with that rule.

Overall, documentation related to device software function(s) should provide sufficient evidence to describe the role of the software in the context of the device's intended use and testing to demonstrate that the software functions as designed.

G. Cybersecurity

Significance: Dental curing lights contain software or firmware and have the ability to connect to the internet either directly or indirectly through the connectivity features present in the device design. Failure to maintain cybersecurity can result in risks such as compromised device functionality, loss of device availability, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats. This in turn may have the potential to result in patient injury.

Recommendation: If the device meets the definition of a cyber device under section 524B(c) of the FD&C Act, cybersecurity documentation under section 524B(b) of the FD&C Act is required as a part of the premarket submission. Refer to the FDA cybersecurity guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," for a discussion of the cybersecurity documentation that you should provide in your submission.

H. Electrical Safety and Electromagnetic Compatibility (EMC)

Significance: Dental curing lights are medical electrical equipment and therefore may expose the operator and patient to hazards associated with the use of electrical energy or may fail to operate properly in the presence of electromagnetic disturbance.

Recommendation: Dental curing lights should be tested to demonstrate that they perform as anticipated in their intended use environment. We recommend that this testing be performed as described in the currently FDA-recognized versions of the following standards for medical electrical equipment safety and electromagnetic compatibility:

- IEC 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (with relevant U.S. national differences applied)*
- IEC 80601-2-60 *Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment*
- IEC 60601-1-2 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

If submitting a Declaration of Conformity to the above standards, we recommend that appropriate supplemental documentation such as an assessment of the results and how conformity was determined. Information regarding test methods used should be provided because this series of standards includes general methods with multiple options and, in some cases, does not include specific acceptance criteria or address assessment of results. For

additional information on providing electromagnetic compatibility information in a premarket submission, see FDA's guidance, "Electromagnetic Compatibility (EMC) of Medical Devices."

I. Wireless Technology

Significance: In the design, testing, and use of wireless medical devices, the correct, timely, and secure transmission of medical data and information is essential for the safe and effective use of medical devices and systems.

Recommendation: If your dental curing light incorporates radiofrequency wireless technology such as Bluetooth, IEEE 802.11 (Wi-Fi) or RFID (radio frequency identification) technology, testing beyond what is specified in the IEC 60601 standards is recommended to demonstrate that the wireless device functions will perform as intended in environments with other wireless products.

We recommend that you consult FDA's guidance "Radio Frequency Wireless Technology in Medical Devices" for additional recommendations on this topic.

J. Non-Clinical Performance Testing

Non-clinical performance testing is recommended for dental curing lights to fully characterize the device. Descriptive characteristics alone are not sufficient to ensure that the devices can perform as intended for the end user. For information on the recommended content and format of test reports for the testing described in this section, refer to FDA's guidance, "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions."

(1) Radiant power output

Significance: Radiant power output (radiant flux) is a measure of the ability of dental curing lights to photopolymerize dental restorative resins. Inadequate radiant power output from dental curing lights can result in incomplete curing of dental restorative resins and lead to premature failure of the restorative material. Excessive radiant power output can result in a thermal hazard for both the patient and the provider. Testing on the type, amount, and uniformity of radiant power output provides assurance that the dental curing light will provide the appropriate amount of energy for its intended purpose.

Recommendation: We recommend that you characterize the radiant power output delivered by the dental curing light source using test methods that conform to the following currently FDA-recognized consensus standard, ISO 10650 *Dentistry – Powered Polymerization Activators.*

We recommend that you provide the results of testing that characterizes the radiant power output of your dental curing light. We recommend that you provide the following information:

- Total radiant power output (or radiant flux) (mW) throughout the total exposure cycle;

- Maximum light intensity (or irradiance) (mW/cm^2) measured at a distance of 2 mm from the distal end of the device light guide;

- Total spectral irradiance (mW/cm^2- nm) plot at maximum irradiance output (mW/cm^2) versus wavelength (nm) at a distance of 2 mm from the distal end of the device light guide showing the peak wavelength (nm) and ultraviolet wavelengths (i.e., < 385 nm);

- Radiant exposure (or optical radiation dose) output range (J/cm^2) calculated by multiplying irradiance (mW/cm^2) outputs of the various curing modes by recommended curing times (s);

- Irradiance attenuation plot, which is the irradiance (mW/cm^2) versus vertical distance (from 0 mm to 10 mm at 2 mm increments) from the device light guide tip; and

- Thermal image or beam profiler of cross section of light guide tip at maximum radiant exitance showing relative "hot" and "cold" spots across lateral surface of the device light guide tip.

(2) Heat generation

Significance: Heat generation is the ability of dental curing lights to accumulate heat during normal operation. Excessive heat generation by the dental curing light can present a thermal hazard to the patient and the practitioner. Testing on heat generated during normal operation helps ensure that the dental curing light will not present a thermal hazard when used for its intended purpose.

Recommendation: We recommend that you provide data to demonstrate that during normal and single fault conditions, the temperature generated by the device remains safe for both the patient and the practitioner. This would include heat generated within the body of the device and at the distal tip. We recommend that you identify the maximum temperature (°C) of the body of the device and at 2 mm from the distal end of the device under normal and single fault conditions when operated under the worst-case scenario, i.e., for the highest radiant exposure (J/cm^2).

(3) Depth of cure

Significance: Depth of cure is a measure of thickness of a dental restorative resin that can be cured by a dental curing light under typical operating conditions. Inadequate depth of cure can result in incomplete curing, structural deficiencies, and premature failure of the dental restorative resin device. Depth of cure testing provides assurance that the dental curing light will provide sufficient energy to harden the compatible resin within the recommended curing time.

Recommendation: We recommend that you provide the depth of cure (mm) on a representative, legally marketed dental restorative resin sample after a clinically relevant curing time. FDA recommends 10s as a clinically relevant curing time. We also recommend that you identify the dental restorative resin that was tested in the submission.

IV. Modifications

21 CFR 807.81(a)(3) provides that a device change or modification "that could significantly affect the safety or effectiveness of the device" or represents a "major change or modification in the intended use of the device" requires a new 510(k).[2] For additional details, see FDA guidances "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."

[2] Section 3308 of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023, added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act (Pub. L. No. 117-328). Section 515C provides FDA with express authority to approve or clear PCCPs for devices requiring premarket approval or premarket notification. For example, section 515C provides that supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA. Section 515C also provides that FDA may require that a PCCP include labeling for safe and effective use of a device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan. If you are interested in proposing a PCCP in your marketing submission, we encourage you to submit a Pre-Submission to engage in further discussion with CDRH. See FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."