Guidance for Industry, FDA Reviewers/Staff and Compliance

# Guidance[1] Document for Surgical Lamp 510(k)s

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**U.S. Department Of Health And Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**

**General Surgical Devices Branch**
**Division of General and Restorative Devices**
**Office of Device Evaluation**

# Preface

## Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to General Surgical Devices Branch, HFZ-410, 9200 Corporate Boulevard, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Mr. Neil R.P. Ogden, MS at (301) 594-1307, ext. 152 or by electronic mail at (nro@cdrh.fda.gov).

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[1] This document is intended to provide guidance. It represents the Agency'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. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

## INTRODUCTION -

This document outlines specific information to be submitted for a surgical lamp premarket notification (510(k)). A 510(k) should provide information to support substantial equivalence of the proposed device to a device legally in commercial distribution. Substantial equivalence is to be established with respect to, but not limited to, intended use, design, energy used/delivered, materials, performance, safety, effectiveness, labeling, and other applicable characteristics.

## PURPOSE -

This guidance is intended to:

1. assist manufacturers, distributors, or importers in organizing premarket notifications for surgical lamps and accessories;

2. achieve consistency in meeting of requirements and in the presentation of information; and

3. guide FDA staff in conducting and documenting the review of surgical lamp premarket notifications.

## OVERVIEW -

Surgical lamps are described in the FDA regulations, 21 CFR 878.4580. A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient. The FDA classified the device as a class II (special controls) device. We encourage manufacturers to follow the draft IEC standard for surgical luminaries (60601-2-41/Ed1) cited in this guidance. (Note: To date, this standard has not been recognized by FDA, as provided by 21 U.S.C. 360d(c). Thus, the procedures for submitting a declaration of conformity in order to meet premarket submission requirements--as outlined in FDA's document entitled "Guidance on the Recognition and Use of Consensus Standards" (February 19, 1998)--currently do not apply to this standard.)

## SURGICAL LAMP TERMINOLOGY AND DEFINITIONS -

See IEC 60601-2-41 draft standard.

## SUGGESTED FORMAT -

- **General information** -
  a. Trade name including the model number of the device.
  b. Common name or the classification name (21 CFR 807.87) of the device.
  c. Establishment registration number.
  d. Address of manufacturing facility/facilities.
  e. The classification in which the device has been placed (Class I, II, III, or not classified) under section 513 of the act, and, its appropriate panel, if known. If the submitter determines that the device has not been classified, a statement of that determination and the basis for that determination.

f. The reason for the premarket notification - a new device or a modification to an existing device. If the 510(k) is for a modification, describe in detail the reason for the modification and provide the 510(k) number for the original device.
g. Identification of a legally marketed predicate device to which you claim equivalence.
h. Compliance with standards or guidelines.

- **510(k) Summary and/or certification statement in accordance with Safe Medical Devices Act of 1990** - see 57 FR 18066, April 28, 1992 as amended in 59 FR 64295 on December 14, 1994.

- **Proposed Labeling** - see ODE Bluebook Memo G91-1, Device Labeling Guidance. A copy of this guidance may be obtained from DSMA.
  a. Intended use.
  b. Prescription labeling in accordance with 21 CFR 801.109 (b)(1).
  c. Identification labels.
  d. Provide all labeling including adequate directions for use, advertisements, appropriate directions for re-processing/disinfection/sterilization, maintenance, etc. Include all cautions, warnings, precautions, contraindications or limitations.
  e. Sterilization instructions. The repeated re-sterilization should not compromise the performance of the device.
  f. Provide the intervals for routine maintenance.
  g. Detailed instructions in addition to sterilization including the following:
     * Assembly/disassembly
     * Detailed cleaning

- **Detailed Device Description** - Please provide the following:

  a. Performance Specifications - Please see the IEC 60601-2-41 draft standard for specific value ranges.
     (1) illumination area, diameter and depth of the light beam
     (2) light focusing mechanism
     (3) energy of the light in Lux
     (4) color temperature of light($^{o}$K)
     (5) amount of Ultraviolet (≤400nm) light emitted (watts/cm$^{2}$)
     (6) light source
     (7) ultraviolet light filter mechanism

  b. Detailed schematic, assembly, and engineering drawings. Please see the IEC 60601-2-41 draft standard for specifics.
     (1) lamp head(s)
     (2) support mechanism(s)
     (3) illumination component(s)

- **Comparative Information -** The following should be provided in side by side tabular form:
  a. Identify predicate device(s) with the same intended use for comparison.
  b. Provide side by side comparisons including similarities and differences.
     (1) Comparisons in physical description, performance specifications, materials, dimensions, and other characteristics.
     (2) Comparisons in testing and operating parameters.
  c. Explain the consequences and effects of changes or modifications and how the differences affect the use and safety of the device.

- **Biocompatibility** - Typically surgical lamps do not contact patients, so biocompatibility is not an issue. If there is a patient contacting part of a surgical lamp, please see our Bluebook Memo G95-1, entitled "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing" for guidance on Biocompatibility.

- **Sterilization Information** - Please see our Bluebook Memo K90-1, 510(k) Sterility Review Guidance. A copy of this guidance may be obtained from DSMA.

  a. Sterile devices - Typically surgical lamps have no components provided sterile. If your device does include sterile components, pleased provide the following:
     (1) Method of sterilization used (ETO, RAD, Steam).
     (2) SAL level attained.

  b. Reusable sterile devices - Typically this would be the lamp handle. Please follow the *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance*.

- **Software Validation** - See the Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review. A copy of this guidance may be obtained from DSMA.

- **Standards -**
  Draft IEC 60601-2-41/Ed1 Standard- Particular Requirements for the safety of surgical luminaries and luminaries for diagnosis.

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

References are available at our web site:
http://www.cdrh.fda.gov/cdrh/topindx.html#G for guidances.
http://www.cdrh.fda.gov/cdrh/blbkmem.html for Bluebook Memos.