This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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. This guidance will be updated in the next revision to include the standard elements of GGP's.

510(k) Checklist for Endoscopic Light Sources Used In Gastroenterology and Urology

The purpose of this 510(k) checklist is to identify the type of information to be provided in a premarket notification (510(k)) to support a determination of substantial equivalence for endoscopic light sources used in gastroenterology and urology. The criteria listed within this 510(k) checklist are consistent with the requirements that the Urology and Lithotripsy Devices Branch has utilized for these devices for some time.

General guidance for the preparation of a 510(k) submission is provided in the DRAERD "Draft Guidance for the Content of Premarket Notifications." Additionally, guidance on the preparation of a 510(k) is available in our "Center for Devices and Radiological Health Premarket Submissions Cover Sheet," which we are requesting that manufacturers use in the preparation of any type of premarket submission, as part of a pilot program. Additional guidance on device modifications is provided in the draft document "Deciding When to Submit a 510(k) for Change to an Existing Device." These documents are available from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Light sources have been designated as Tier 1 products unless they are software controlled. For information on the Tier 1 process and the specific information needed for 510(k)s for the Division's Tier 1 devices, refer to the "DRAERD Triage Pilot Program." A copy may be obtained from DSMA. Note that Tier 1 devices still require a complete 510(k) to be submitted.

Adequate?

1. **Administrative information:**

   a. Classification name - Accessory to Endoscope (Endoscopic Light Source) ____

   b. Device trade name ____

   c. Sponsor/manufacturer name and address ____

d. Panel/Classification - 78, Class II, 21 CFR 876.1500 ____

e. Procodes (Light Source):
   GCT (Endoscope, Xenon Arc) ____
   FCW (Fiberoptic, Routine) ____
   FCQ (Incandescent, Diagnostic) ____
   FFS (Illuminator, Fiberoptic) ____
   FTI (Incandescent Lamp) ____

f. Establishment registration number ____

g. Special controls - None established ____

2. **Reason for the 510(k) submission** (new device or a modification to an existing device) ____

3. **Intended use of the device:**

Endoscopic light sources are intended to provide illumination for fiberoptic endoscopy to gastroenterological and urological cavities, hollow organs, and canals.

4. **Device description:**

a. Diagrams, drawings, photographs of the device ____

b. List of the device's components, controls, and attachments (e.g., power, endoscope connector, shutter/illumination level adjustment (manual/auto), photographic strobe, video attachment, UV/IR filters, compatible connector(s), etc.) ____

c. Light/lamp data
   1. Light intensity (low/high) ____
   2. Lamp type (e.g., Halogen, Mercury, Xenon, Tungsten, Metal-Halide, etc.) ____
   3. Number of lamps ____
   4. Lamp life (hours) ____
   5. Illumination level adjustment (number of steps) ____
   6. Color temperature (kelvin) ____
   7. Lumens (minimum/maximum) ____

d. Electrical/thermal specifications
   1. Power source (VAC/Hz) ____
   2. UV/IR radiation (box/cable)
      Provide spectral analysis (power versus wavelength) demonstrating that the UV and IR energies are acceptably low at the start of their respective ranges.

Note that the graph should range from at least 250 nm (to address UV concerns) and up to at least 770 nm (to address IR concerns). ____

3. Heat dissipation (◦C/◦F) (box/cable) ____

e. Dimensional characteristics (size, weight) ____

f. Safety features (e.g., alarms, lamp door open/ power off, internal cooling fan (power on), UV/IR protection filter, etc.) ____

g. Description of the ergonomic features of the device (e.g., can the device be easily operated, visual/audible alarms) ____

h. Explanation of whether or not the device or any of its features are software controlled (if so, this aspect of the device must be described according to the draft FDA guidance document "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review"). If the device does not contain software, please explicitly state that there is no software, because the device should then be eligible for Tier 1 review. ____

5. **Electrical safety/Performance testing**

a. Data from testing that addresses electrical safety (leakage current, grounding, isolation, etc.) or certification that the finished product meets all applicable electrical safety requirements specified in the latest version of a recognized electrical standard for medical devices (e.g., CSA C22.2 No.125, IEC 601-1, UL 544, UL 2601-1 (Harmonized Standard for Medical Electrical Equipment), etc.). ____

b. Electromagnetic compatibility and interference (EMC/EMI) should be addressed. To address this item, immunity and emissions testing should be performed to evaluate the potential of the device to be affected by, as well as to cause, electromagnetic interference in the intended use environment. Additionally, if applicable, the device's labeling should inform the user of the potential of the device to interfere with surrounding equipment. Appropriate justification for why such testing is not needed will be considered. ____

c. Other tests identified (provide protocol and results) ____

6. **Proposed labeling, instructions for use, advertisements:** (per the "Device Labeling Guidance," Blue Book Memo G91-1)

a. Instructions for use (preparation, operation, and shut down) _____

b. Intended use statement (Section 3 above contains acceptable wording) ____

c. Prescription device statement (21 CFR 801.109) ____

d. Specifications (dimensional, electrical) ____

e. Features (lamp type, accessories, controls, etc.) ____

f. Statement of the approximate lamp life ____

g. Maintenance procedures (Cleaning, fuse/circuit breaker, lamp/lamp holder replacement, storage, etc.) ____

h. Troubleshooting procedures and solutions ____

7. **Comparison to legally marketed endoscopic light source:**

a. Name/manufacturer of predicate device ____

b. Labeling of predicate device ____

c. Intended use of predicate device ____

d. Description of predicate device ____

e. Diagrams/photographs of predicate device ____

f. 510(k) number (if known) of the predicate device (or statement that the predicate device is Pre-Amendments) ____

g. A detailed comparison of the similarities/ differences (including all the information contained in Section 4 above) between the 510(k) device and the predicate device (in tabular format) ____

8. **510(k) summary/statement** (21 CFR 807.92 and 807.93) ____

9. **Truthful and accurate statement**
(signed and in accordance with 21 CFR 807.87(j) ____

For further information contact:

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