510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments (Text Only)

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.

9/19/94

510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments

Note: general guidance for the preparation of a 510(k) submission is provided in the DRAERD "Draft Guidance for the Content of Premarket Notifications." Additional guidance on device modifications is provided in the draft document "Deciding When to Submit a 510(k) for Change to an Existing Device." Both documents are available from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 796-7100.

1. Administrative information:

    a. Classification name - Accessory to Endoscope (Transurethral Surgical Instrument)
    b. Device trade name
    c. Sponsor/manufacturer name and address
    d. Procode/Classification - FHX 78, Class II (21 CFR 876.1500)

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

3. Intended use of the device: Sterile lubricating jelly is intended to facilitate the passage of transurethral surgical instruments

4. Device description:

    a. List of device ingredients

1. Quantity of each ingredient (%)
2. Identification of active/inactive ingredients
3. Function of each ingredient (e.g., preservative, thickener, neutralizer, humectant, antibacterial)
4. Statement as to whether the device has any drug components and identification of these drug components

b. Explanation of the mode of action

5. Proposed labeling, instructions for use, advertisements:

a. Instructions for use
b. Intended use statement (See #3 above for example)
c. Prescription device statement (21 CFR 801.109)
d. Labeled for single use
e. Sterile
f. Statement describing solubility (water-soluble or petroleum based)
g. Quantity of jelly provided

6. Physical and Other testing:

a. Preservative effectiveness
b. Stability analysis (pH, viscosity, H2O solubility, lubricity)
c. Antimicrobial effectiveness (if applicable)
d. Other tests identified (provide protocol and results)

7. Biocompatibility:

a. Evidence that the same formulation (i.e., ingredients and concentration) of lubricating jelly is used in another, similar legally marketed device (provide the device name, manufacturer, and (if possible) 510(k) number); OR
b. The results of the following biocompatibility tests on the final formulation (this is the minimum level of required testing):

(1) Mucosal irritation test,
(2) Sensitization test,
(3) Cytotoxicity test,
(4) Acute systemic toxicity test, and
(5) Short-term implantation test

8. Sterility information:

a. The method of sterilization
b. The method used to validate the sterilization cycle
c. The sterility assurance level (i.e., SAL) achieved by the sterilization cycle
d. The levels of the ethylene oxide, ethylene chlorhydrin, and ethylene glycol residuals on the device (if applicable)
e. The radiation level (in megarads) used (if applicable)
f. A description of the packaging material used to ensure the sterility of the device
g. The method used to determine that the device is pyrogen free, if this will be claimed in the labeling

9. Comparison to legally marketed sterile lubricating jellies:

a. Name/manufacturer of predicate device
b. Labeling of predicate device
c. Intended use of predicate device
d. Description of predicate device
e. Description and/or diagrams/photographs of predicate device package and quantity provided
f. 510(k) number (if known) of the predicate device (or statement that the predicate device is preamendments)
g. A detailed comparison of the similarities/ differences (including all ingredients and relative concentrations) between the 510(k) device and the predicate device (in tabular format) 10. 510(k) summary/statement For further information contact:

Urology and Lithotripsy Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation Center for Devices and Radiological Health
301-796-5620

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)