

Classification of Hemorrhoid Devices, LKX FDA Questions

Gastroenterology and Urology Devices Panel of Medical Devices Advisory Committee
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Please refer to the [Regulatory Reference Sheet](#) for additional information regarding classification procedures and definitions.

1. FDA has identified the following risks to health *for heating and cooling hemorrhoid devices and electrically powered hemorrhoid devices that deliver heat under product code "LKX"*:

Heating and cooling hemorrhoid devices (LKX):

- Device Failure/Tissue Injury
- Operator Error
- Adverse Tissue Reaction
- Infection

Electrically powered hemorrhoid devices that deliver heat (LKX):

- Electrical Shock Hazard
- Adverse Tissue Reaction
- Device Failure/Tissue injury
- Operator Error
- Infection

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of *heating and cooling hemorrhoid devices (including electrically powered hemorrhoid devices that deliver heat)* under product code "LKX."

In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these hemorrhoid devices.

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:
 - insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of

special controls would provide such assurance, AND

- the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

A device should be Class II if:

- general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND
- there is sufficient information to establish special controls to provide such assurance.

A device should be Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
- insufficient information exists to:
 - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
 - establish special controls to provide such assurance, BUT
 - I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, AND
 - II. does not present a potential unreasonable risk of illness or injury.

FDA does not believe that special controls will be required for *hemorrhoid devices that contain a liquid to deliver heat or cold therapy* under product code “LXX” and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness for *hemorrhoid devices that contain a liquid to deliver heat or cold therapy*. As such, FDA believes that Class I is the appropriate classification for *hemorrhoid devices that contain a liquid to deliver heat or cold therapy* under product code “LXX.”

- a. Please discuss whether you agree with FDA’s proposed classification of Class I with general controls for hemorrhoid devices that contain a liquid to deliver heat or cold therapy under product code “LXX.” If you do not agree with FDA’s proposed classification, please provide your rationale for recommending a different classification.

FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for *electrically powered hemorrhoid devices that deliver heat* under product code “LXX.” As such, FDA believes that Class II is the appropriate classification for *electrically powered hemorrhoid devices that deliver heat* under product code “LXX.” Following is a risk/mitigation table, which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks:

Identified Risk	Recommended Mitigation Measure
Electrical Shock Hazard	<ul style="list-style-type: none"> ● Performance Testing ● Labeling
Adverse Tissue Reaction	<ul style="list-style-type: none"> ● Biocompatibility ● Labeling
Device Failure/Tissue injury	<ul style="list-style-type: none"> ● Performance Testing ● Labeling
Operator Error	<ul style="list-style-type: none"> ● Labeling
Infection	<ul style="list-style-type: none"> ● Labeling

- b. Please discuss whether the following special controls appropriately mitigate the identified risks to health for *electrically powered hemorrhoid devices that deliver heat* under product code “LXX” and whether additional or different special controls are recommended.
- i. The patient contacting components of the device must be demonstrated to be biocompatible.
 - ii. Performance data must demonstrate that the device performs as intended under anticipated conditions of use. At a minimum, the following performance characteristics must be tested:
 - performance bench testing must demonstrate that the device is durable for repeated use;
 - performance testing must verify the maximum treatment temperature is not exceeded;
 - performance testing must evaluate the mechanical integrity of the device, including the structural strength;
 - appropriate analysis and non-clinical testing must be conducted to validate electrical safety and electromagnetic compatibility (EMC).
 - iii. Labeling must include the following:
 - a description of the device and operational parameters;

- detailed instructions for the user to properly clean, disinfect and maintain the device over the intended use life;
 - a summary which describes the possible susceptibility to electrical hazards associated and to electromagnetic interference (EMI) with the use of the device.
- c. Please discuss whether you agree with FDA's proposed classification of Class II with special controls for *electrically powered hemorrhoid devices that deliver heat* under product code "LXX." If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.