

FDA Executive Summary

Prepared for the
February 26, 2016 Meeting of the
Gastroenterology Devices Panel

Classification of Hemorrhoid Devices

Product Codes:

LKX - hemorrhoid heating and cooling devices

and

LRL - hemorrhoid cushion devices

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1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the Gastroenterology-Urology Devices Advisory Panel (the Panel) for the purpose of securing recommendations regarding the classification of two types of hemorrhoid devices, heating or cooling hemorrhoid devices and hemorrhoid cushions, which are pre-amendments device types that remain unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of hemorrhoid devices under product codes “LKX” and “LRL.”

FDA is holding this panel meeting to obtain input on the risks to health and benefits of two types of hemorrhoid devices, heating or cooling hemorrhoid devices (product code “LKX”) and hemorrhoid cushions (product code “LRL.”) The Panel will discuss whether these two types of hemorrhoid devices should be classified into Class III (subject to General Controls and Premarket Approval), Class II (subject to General and Special Controls) or Class I (subject only to General Controls). If the Panel believes that classification into Class II is appropriate for these two types of hemorrhoid devices under product codes “LKX” and “LRL,” the Panel will also be asked to discuss appropriate controls that would be necessary to mitigate the risks to health.

1.1. Current Regulatory Pathways

Hemorrhoid devices under product codes “LKX” and “LRL” are pre-amendments, unclassified device types. This means that these device types were marketed prior to the Medical Device Amendments of 1976, but were not classified by the original classification panels. Currently these devices are being regulated through the 510(k) pathway, and are cleared for marketing if they are “substantially equivalent” to a legally marketed predicate device.

1.2. Device Description

Hemorrhoid devices are regulated under product codes “LKX” and “LRL” as “Device, Thermal, Hemorrhoids” and “Cushion, Hemorrhoid,” respectively. Hemorrhoid cooling devices are also regulated under the product code “LKX.” FDA is proposing to specifically identify both types of devices (cooling and heating) in the regulation title and replace the term “thermal” devices (as defined by the product code) with “heating” devices for accurate identification in the proposed regulation. Since they are unclassified, there is no regulation associated with these product codes. Heating and cooling hemorrhoid devices under product code “LKX” are designed to apply controlled cooling and conductive heating to hemorrhoids through the use of a probe that is partially inserted in to the rectum. Some devices are electrically powered that deliver heat; other devices contain a liquid to deliver heat or cold therapy.

Hemorrhoid cushion devices under product code “LRL” are designed to temporarily relieve pain and pressure caused by hemorrhoids through the use of an inflatable/non-inflatable cushion or plastic seat.

The intended use for both device types is to provide relief from hemorrhoid discomfort.

2. Regulatory History

Please refer to Table 1 below for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared heating and cooling hemorrhoid devices under product code “LRX.”

Table 1

<i>Submission Document Number</i>	<i>Final Decision Date</i>	<i>Trade Name</i>	<i>Applicant/Sponsor</i>
K113660	5/3/2012	COLD PACK PLASTIC APPLICATOR (MEDICAL GRADE)-NON-CHEMICAL	CRYOTHERAPY PRODUCTS INC.
K072414	4/7/2008	CRYOSTAT	LIL DRUG STORE PRODUCTS INC.
K042564	9/30/2005	HEMOR-RITE CRYOTHERAPY	FAMA HOLDINGS INTERNATIONAL CORP
K012746	11/14/2001	ICE BATON	BEHIVE LTD
K981428	7/7/1998	ANU ICE	CRYOTHERAPY PAIN RELIEF PRODUCTS INC.
K973590	2/5/1998	HEMORRELIEF DEVICE	A. STEIN - REGULATORY AFFAIRS CONSULTING
K964634	6/6/1997	ANOKRYO	MK CONQUEST INTL. INC.
K953241*	9/29/1995	EXSPOR	ALCIDE CORP.
K944874	8/7/1995	ZEROID HEMORRHOIDAL DEVICE	MEDICAL APPLIANCE RESEARCH CORP.
K921189	8/31/1992	THERMA-H	ZEWA AG
K905276	11/7/1991	THERMA-H	KURE SWISS MEDICAL AG CORP.
K883984	12/22/1988	HEMORX COLD PACK	BIO-DYNE INC.
K862490	8/18/1986	ANU-RX	J. & JP. INC.
K855150	4/1/1986	HPK-A DEVICE DFOR THE TREATMENT OF HEMORRHOIDS	HPK INTERNATIONAL INC.
K854569	2/5/1986	HEMOR-ICE	TECHNOLOGY 2000
K852679	8/9/1985	MULTIPLE(HEMORX) IF APPROVED BY TRADEMARK OFFICE	J. & JP. INC.
K822649	11/3/1982	DEVICE FOR THE TREATMENT OF HEMORRHOIDS	DUNMORE CORP.
K822217	9/24/1982	THERMOTHERAPY	LUTHER MEDICAL PRODUCTS INC.
K812567	11/10/1981	RELIEF	AMERICAN PHARMACEUTICAL CO. INC.
K810613*	4/3/1981	ANTIMICROBIAL REMOVAL DEVICE	MARION LABORATORIES INC.

*These products likely have been incorrectly assigned the product code “LXX.” FDA intends to correct this administrative error accordingly.

Please refer to Table 2 below for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared hemorrhoid cushion devices under product code “LRL”:

Table 2

<i>Submission Document Number</i>	<i>Final Decision Date</i>	<i>Trade Name</i>	<i>Applicant/Sponsor</i>
K072690	12/7/2007	HEMAWAY SEAT	HEMAWAY LLC
K932396	9/30/1993	PERI-COMFORT™ SEATING CUSHION	CHI'AM INTL.
K864470	6/23/1987	HEMOREST™	HEALTH AID PRODUCTS

3. Indications for Use

The indications for use (IFU) statement identifies the condition and patient population for which a device should be appropriately used. Representative indications for use statements cleared in the 510(k)s noted in Table 1 for heating and cooling hemorrhoid devices under product code “LKX” are as follows:

- The apparatus is intended to apply controlled, conductive heating to hemorrhoids.
- Intended to provide temporary relief of the symptoms of hemorrhoids through the application of mild heating.
- Treatment of external hemorrhoids by applying cold therapy (cryotherapy) directly to swollen hemorrhoidal veins
- Relief of hemorrhoid discomfort through direct application of controlled cold to affected tissues

Representative indications for use statements cleared in the 510(k)s noted in Table 2 for hemorrhoid cushion devices under product code “LRL” are as follows:

- For the temporary relief from the pain and pressure of hemorrhoids. The device is for external use only.
- Intended for the home convalescent patient with perineal discomfort.

4. Clinical Background

This section summarizes the history of the use of hemorrhoid devices under product codes “LKX” and “LRL.”

4.1. Standard of Care

Hemorrhoids are swollen veins in the anal canal. This is a common problem that can be painful, but is not usually serious. Hemorrhoids are either located externally and covered with peri-anal skin or internally located proximal to the dentate line and covered by relatively insensate mucosa. Internal hemorrhoids may bulge into or out of the anal canal with straining and result in bleeding.

Most patients with hemorrhoid symptoms will obtain relief with a high-fiber diet and application of topical anti-inflammatory and analgesic ointments, although well-designed studies have found no evidence to support the use of any of the of over-the-counter topical preparations. Patients with refractory symptoms may require more

advanced therapeutic intervention for internal hemorrhoids including coagulation or cauterization, injection or banding. Large internal hemorrhoids or extremely uncomfortable external hemorrhoids may also require surgical intervention.

Non-surgical symptomatic therapy for both internal and external hemorrhoids also can involve the use of cryotherapy or local heat application. There are many forms of cryotherapy, although they all involve an external pad or inserted rectal tubing that contains a frozen liquid. These result in vasoconstriction in the tissues, tissue hypoxia, analgesia, and muscle relaxation.

The evidence for the use of the local application of heat treatments for hemorrhoids has been less compelling, although the use of a warm water Sitz bath at 43 °C for 15 to 20 minutes is generally believed to relieve pain, itching and muscle spasms, are often recommended to speed healing after hemorrhoid surgery or an episiotomy. Sitz baths pose almost no risk since the typical range of the bath water is less than that of shower water temperature of 43 to 49 °C.

In addition to the use of cryotherapy or local heat application, hemorrhoid cushions or pads are commonly recommended to patients with peri-anal discomfort or pain based on the intuitive belief that this will limit the direct pressure from sitting on the peri-anal area.

4.2. Risks

The cooling devices consist primarily of rectal inserts that are placed in a refrigerator freezer, and the heating devices have a maximum temperature of 46 °C. Therefore, there are minimal safety concerns since it is extremely unlikely the use of hemorrhoid heating devices, or hemorrhoid cooling devices, under product codes “LKX” would result in any injury to the mucosal surfaces.

There are minimal safety concerns with hemorrhoid cushions since it is unlikely that a seat or cushion will cause injury.

5. Literature Survey

In order to identify the risks to health for both hemorrhoid device types, FDA conducted a literature search using the PubMed search engine with the terms “hemorrhoid cushion,” “hemorrhoid heating,” “hemorrhoid cooling.” Four applicable studies were identified from the search. The literature search did not provide evidence of any safety concerns regarding the use of heating or cooling hemorrhoid devices and hemorrhoid cushions. No adverse events were identified in the literature review. FDA is unable to draw conclusions from these studies regarding effectiveness as the majority of the studies were utilizing hemorrhoid cooling devices post-surgical or with non-surgical intervention.

6. Risks to Health Identified Using “Manufacturer and User Facility Device Experience” (MAUDE) Database

6.1. Overview of MAUDE Database

The MAUDE database is maintained by the Office of Surveillance and Biometrics at FDA. This database contains adverse events and reportable product problems with medical devices. The database was fully implemented in August 1996, and contains individual adverse event reports submitted by manufacturers, user facilities, importers, and voluntary reporters. Medical device manufacturers are required to report known adverse events as part of the general controls that most medical devices are subject to; patients and consumers are also encouraged to voluntarily report adverse events.

One does need to note the limitations to MDR reporting, including the fact that not all events are captured since there is a voluntary component to the reporting system. In addition, confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report.

6.2. MAUDE Search Results: Hemorrhoid Devices

The FDA conducted queries of the MAUDE database on August 6, 2015 and September 9, 2015 for “LXX” and “LRL,” respectively, to identify adverse events related to use of hemorrhoid devices. The search was restricted to the parameter of device product codes “LXX” and “LRL” There was no date limitation for the query. The query did not identify any MDRs related to these product codes.

7. Summary

In light of the information available, the Panel will be asked to comment on whether heating and cooling hemorrhoid devices under product code “LXX” and hemorrhoid cushion devices under product code “LRL”:

meet the statutory definition of a Class III device:

- insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, 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

or would be more appropriately regulated as Class II, in which:

- general and special controls, which may include performance standards, postmarket surveillance, patient registries and/or development of guidelines, are sufficient to provide reasonable assurance of safety and effectiveness;

or as Class I, in which

- the device is subject only to general controls, which include registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.

For the purposes of classification, FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;
2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
4. The reliability of the device.

7.1. Special Controls

Heating and Cooling Hemorrhoid Devices – Product Code LKX

FDA believes that different regulatory controls are appropriate for electrically powered devices that deliver heat and devices that contain a liquid to deliver heat or cold therapy as outlined below.

Electrically Powered Hemorrhoid Devices

FDA believes that special controls, in addition to general controls, can be established to mitigate the risks to health identified, and provide a reasonable assurance of the safety and effectiveness of electrically powered hemorrhoid devices that deliver heat under product code “LKX”. The 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:

Table 3: Risk/mitigation recommendations for electrically powered hemorrhoid devices that deliver heat under product code “LKX”

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

Infection	• Cleaning or sterility
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The panel will be asked whether this list is a complete and accurate list of the risks to health presented by electrically powered hemorrhoid devices that deliver heat under product code “LXX” and whether any other risks should be included in the overall risk assessment of the device type.

Based on the recommended mitigation measures, FDA believes that the following special controls would provide reasonable assurance of safety and effectiveness for heating hemorrhoid devices that deliver electrically powered thermal energy under product code “LXX”:

- The patient contacting materials of the device must be demonstrated to be biocompatible.
- 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).
- 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.

If the panel believes that Class II is appropriate for electrically powered hemorrhoid devices that deliver heat under product code “LXX,” the panel will be asked whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

Heating and Cooling Hemorrhoid Devices that Contain a Liquid to Deliver Heat or Cold Therapy

FDA believes that special controls will not be required and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness of heating and cooling hemorrhoid devices that contain a liquid to deliver heat or cold therapy.

The panel will be asked whether general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of hemorrhoid heating and cooling devices under product code “LXX” (designed to apply controlled cooling and conductive heating to hemorrhoids using a liquid) and whether any risks should be included in the overall risk assessment of the device type.

Hemorrhoid Cushion Devices – Product Code LRL

FDA believes that special controls will not be required and that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of hemorrhoid cushion devices under product code “LRL”.

The panel will be asked whether general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of hemorrhoid cushion devices under product code “LRL” and whether any risks should be included in the overall risk assessment of the device type.

7.2. **Overview of Proposed Classification**

Heating and Cooling Hemorrhoid Devices – Product Code LXX

Based on the identified risks to health and recommended mitigation measures, we recommend that electrically powered hemorrhoid devices that deliver heat (product code “LXX”) indicated for delivering conductive heating to hemorrhoids for use in patients with hemorrhoids be regulated as Class II devices (special controls).

Based on the identified risks to health and recommended mitigation measures, we recommend that heating and cooling hemorrhoid devices under product code “LXX” indicated for delivering cooling and conductive heating using a liquid to hemorrhoids for use in patients with hemorrhoids be regulated as Class I devices (general controls).

876.XXXX Heating and cooling hemorrhoid device

(a) *Identification.* Cooling and heating hemorrhoid devices consist of a probe that is inserted partially into the rectum and use cooling or conductive heating to temporarily relieve pain and pressure caused by hemorrhoids. The probe may contain a liquid to deliver heat or cold therapy. The device may alternatively use an electrical element to deliver heat therapy.

(b) *Classification.* (1) Class II (special controls) for electrically powered hemorrhoid devices that deliver heat. The special controls for this device are:

- a. The patient contacting materials of the device must be demonstrated to be biocompatible.

- b. 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:
 - i. performance bench testing must demonstrate that the device is durable for repeated use;
 - ii. performance testing must verify the maximum treatment temperature is not exceeded;
 - iii. performance testing must evaluate the mechanical integrity of the device, including the structural strength;
 - iv. appropriate analysis and non-clinical testing must be conducted to validate electrical safety and electromagnetic compatibility (EMC).
- c. Labeling must include the following:
 - i. a description of the device and operational parameters;
 - ii. detailed instructions for the user to properly clean, disinfect, and maintain the device over the intended use life;
 - iii. a summary which describes the possible susceptibility to electrical hazards associated and to electromagnetic interference (EMI) with the use of the device.

(2) Class I (general controls) for hemorrhoid devices that contain a liquid to deliver heat or cold therapy. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 876.9.

Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of hemorrhoid heating and cooling devices under product code “LXX” for use in temporarily relieving pain and pressure caused by hemorrhoids.

Hemorrhoid Cushion Devices – Product Code LRL

Based on available information and the identified risks to health, we recommend that hemorrhoid cushion devices under product code “LRL,” indicated to relieve pain and pressure caused by hemorrhoids, be regulated as Class I devices (general controls).

876.XXXX Hemorrhoid cushion

(a) *Identification.* A hemorrhoid cushion is an inflatable/non-inflatable pillow or plastic seat used to temporarily relieve pain and pressure caused by hemorrhoids.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 876.9.

8. References

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