Classification of Devices Under Product Codes LKX and LRL

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CDRH Product Codes (Procodes)

- **Procodes**
  - A three letter product code (procode) for each generic category of device, along with a Procode name
- **Procode Names**
  - Procode names are generally created at the level of the generic device group, which typically represents a set of devices having the same or similar intended use or common technology and which allows general product identification

CDRH Product Codes (Procodes)

- LKX – Hemorrhoid heating and cooling devices
- LRL – Hemorrhoid cushion devices

Outline of Product Code Presentations

- Introduction
- Device Descriptions
- Indications for Use
- Risks to Health and Mitigations
- Proposed Classification

Hemorrhoid Heating and Cooling Devices (LKX)

- Designed to apply controlled cooling and conductive heating to hemorrhoids through the use of a probe that is partially inserted into the rectum.
- Regulated under product code “LKX” as “Device, Thermal, Hemorrhoids.”
- Since it is unclassified, there is no regulation associated with the product code.
- There have been 18 clearances for Hemorrhoid Heating and Cooling Devices (or modifications to previously cleared Hemorrhoid Heating and Cooling devices) via the 510(k) process.
- Note: FDA is considering changing the name of the product code from “Device, Thermal, Hemorrhoids” to “Heating and cooling hemorrhoid device” to more accurately describe the types of devices under this product code.

Device Descriptions

- A device consisting of a module encased in plastic which houses a battery power source and control system. One cable terminates in an anal terminal or probe. Temperature range is adjustable: 37°C to 45°C.

http://www.zewa.com/h-p-eco.html

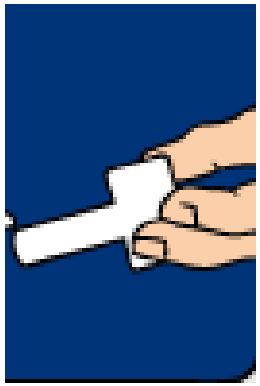
Device Descriptions

- A device consisting of a hard plastic liquid container that is kept in the freezer until use.

- A sealed plastic device that has been anatomically designed to fit the shape of the anal canal; device contains coolant material.

- An anatomically designed sealed plastic bag, enclosed in a medical grade cloth outer wrapper for comfort.

http://www.medritelabs.com/



https://www.anuice.com/

Indications for Use

- 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

Hemorrhoid Cushion Devices "LRL"

- Designed to use an inflatable/non-inflatable cushion or plastic seat to temporarily relieve pain and pressure caused by hemorrhoids.

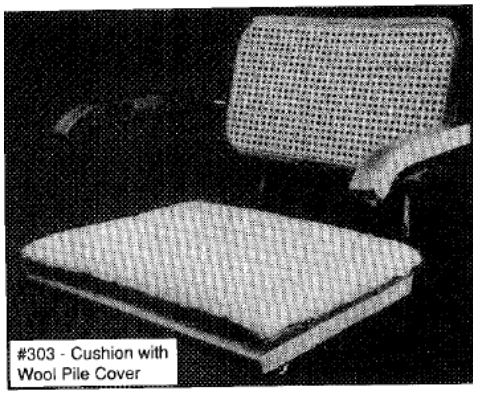
- Regulated under product code "LRL" as "Cushion, hemorrhoid." Since it is unclassified, there is no regulation associated with the product code.

- There have been 3 clearances for hemorrhoid cushion devices (or modifications to previously cleared hemorrhoid cushions) via the 510(k) process.

Device Descriptions

- An inflatable/non-inflatable cushion or plastic seat

- Designed to temporarily relieve pain and pressure caused by hemorrhoids



http://www.amazon.com/HemAway-Seat-The-Relief-Case/dp/B005PGFGIU

Indications for Use

- 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.

Risks and Mitigations

- Manufacturer and User facility Device Experience (MAUDE) database (1996-2014)
- Medical Device Recalls database (2002-2014)
- Information available to FDA regarding cleared devices
- Review of literature

Potential Risks and Mitigations

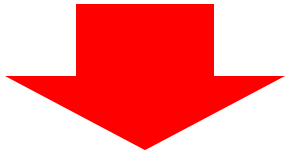
- No MAUDE and Medical Device Recalls databases search results returned.

- Additional results were obtained from searches of 510(k) cleared information available to FDA, or general use search engines or PubMed using key search terms.

  - The literature search did not provide evidence of any safety concerns regarding the use of heating or cooling hemorrhoid devices and hemorrhoid cushions.

Potential Risks and Mitigations

Based on the additional searches, risks to health have been parsed into three groups:

Heating and cooling hemorrhoid devices (product code "LKX")	Electrically powered hemorrhoid devices that deliver heat (product code "LKX")	Hemorrhoid cushions (product code "LRL")
		
Proposed Class I	**Proposed Class II**	**Proposed Class I**

Potential Risks and Mitigations for heating and cooling hemorrhoid devices ("LKX") and hemorrhoid cushions ("LRL")

Non-Electrical heating and cooling hemorrhoid devices ("LKX")

Identified Risk	Recommended Mitigation Measure
Device Failure/Tissue injury	• General Controls (Class I)
Operator Error	• General Controls (Class I)
Adverse Tissue Reaction	• General Controls (Class I)
Infection	• General Controls (Class I)

Hemorrhoid cushions ("LRL")

Identified Risk	Recommended Mitigation Measure
Device Failure/Tissue injury	• General Controls (Class I)
Operator Error	• General Controls (Class I)
Adverse Tissue Reaction	• General Controls (Class I)

Enema Kits Comparison

- ***Heating and cooling hemorrhoid devices are similar to Enema kits (21CFR876.5210).***
- ***Enema kits are devices intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon.***
- ***The device consists of a container for fluid connected to the nozzle either directly or via tubing.***
- ***Enema kits and heating/cooling hemorrhoid devices under product code "LKX" have similar identified risks:***
  - ***Device Failure/Tissue Injury***
  - ***Operator Error***
  - ***Adverse Tissue Reaction (Biocompatibility)***
  - ***Infection***
- ***Enema kits are exempt from the premarket notification procedures and are classified as Class I (general controls) devices.***

http://www.avalinemedical.com/

Potential Risks and Mitigations for electrically powered heating devices under product code "LKX"

Identified Risk	Recommended Mitigation Measure
Electrical Shock Hazard	• Performance Testing • Labeling
Adverse Tissue Reaction	• Biocompatibility • Labeling
Device Failure/Tissue injury	• Performance Testing • Labeling
Operator Error	• Labeling
Infection	• Labeling

- **FDA proposes that the identified risks be regulated as Class II (special controls).**

Proposed Classification Regulation

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 components of the device must be demonstrated to be biocompatible.

Proposed Classification Regulation (cont'd)

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).

Proposed Classification Regulation (cont'd)

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.

Proposed Classification Regulation (cont'd)

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.


FDA

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Back Up Slides

MDR Reporting Requirements

REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer (Mfr) 	Deaths, Serious Injuries, Malfunction	FDA	Within 30 calendar days of becoming aware
User Facility 	Deaths	FDA and Mfr	Within 10 working days
	Serious Injury	Mfr (FDA if unknown)	Within 10 working days
Importer 	Deaths and Serious Injuries	FDA and Mfr	Within 30 calendar days
	Malfunctions	Mfr	Within 30 calendar days
Voluntary 	Any type of event	FDA	Any time

Limitations and Uses of MDRs

- Limitations
  - » Under-reporting of events
  - » Inadequate or insufficient information
  - » Inability to establish causality
  - » Inability to calculate a “rate” of event
  - » Difficulty in assessing trends
- Uses
  - » Qualitative snapshot of real-world AEs for a device/device type
    - Types and severities of malfunctions and/or clinical events
    - Clinical sequelae and treatments required to address issue
  - » Monitor device performance/Signal detection
    - Unexpected events
    - Change in severity or outcomes of expected events
    - User error/human factors issues

Medical Device Reporting (MDR)

- FDA receives several 100K Medical Device Reports (MDRs) annually (suspected device-associated deaths, serious injuries and malfunctions).
- Medical Device Reporting is one of FDA's postmarket surveillance tools to monitor device performance, detect device-related safety issues, and contribute to benefit-risk assessments.
- Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to FDA about medical devices.
- FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures.
- These reports, along with data from other sources, can provide critical information that helps improve patient safety.

MAUDE Database

- The Manufacturer and User Facility Device Experience (MAUDE) database houses MDRs submitted to the FDA by:
  - » mandatory reporters (manufacturers, importers and device user facilities); and
  - » voluntary reporters (health care professionals, patients and consumers).
- The MAUDE database contains:
  - » mandatory reports filed by manufacturers and importers from August 1996 to present;
  - » all mandatory user facility reports from 1991 to present; and
  - » voluntary reports filed after June 1993.

Potential Risks and Mitigations

- No MAUDE and Medical Device Recalls databases search results returned.
- Additional results were obtained from searches of 510(k) cleared information available to FDA, or general use search engines or PubMed.
- Heating (excluding devices that deliver electrically powered heat) and cooling hemorrhoid devices and hemorrhoid cushion devices potential risk can be mitigated by Class I General Controls
  - registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.