Classification of Vapocoolant Devices
FDA Questions

Neurological Devices Panel of the Medical Devices Advisory Committee June 3-4, 2021

1. FDA has identified the following risks to health for vapocoolant devices:

Identified Risk	**Description/Examples**
Pain or discomfort	This can result from burns and/or blistering.
Skin irritation	This can result from burns and/or blistering.
Thermal injury	This can result from frostbite or burns particularly when used in combination with electrical cautery leading to ignition, leading to redness, blistering and edema.
Electrical shock or burn	This can result from electrical failure or malfunction.
Interference with other devices	Electromagnetic disturbances that may cause unacceptable degradation in device performance, leading to delayed or ineffective treatment.
Device failure/malfunction leading to ineffective treatment	Device malfunction can cause spray to contact unintended areas of the body which can lead to burns and minor injury.
Asthma	This can result from an allergic response to the product or aerosol delivery system.
Hallucination	This can result from improper use of the device and subsequent inhalation toxicity.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of vapocoolant devices under product code "MLY". In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these vapocoolant 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

    - if, in addition, 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 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 this device type. As such, FDA believes that Class II is the appropriate classification for vapocoolant devices. 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.

Risk/mitigation recommendations for vapocoolant devices under product code "MLY"

Identified Risk	**Recommended Mitigation Measure**
Pain or discomfort	Labeling
Skin irritation, including: • Bruising • Numbness • Erythema • Swelling	Labeling
Thermal injury, including: • Skin blanching • Sores • Frostbite • Burns	Non-clinical performance testing Labeling
Electrical shock or burn	Electrical safety testing

Identified Risk	Recommended Mitigation Measure
Interference with other devices	Electromagnetic compatibility (EMC) testing
Device failure/malfunction leading to ineffective treatment	Non-clinical performance testing Labeling
Asthma	Labeling
Hallucination	Labeling

Please discuss whether the identified special controls for vapocoolant devices appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. Non-clinical performance testing must characterize the change in skin surface temperature control when the device is used as intended.

2. Non-clinical performance testing must demonstrate electrical safety and electromagnetic compatibility for powered devices.

3. Healthcare provider and patient labeling must include:
   a. Information on how the device operates and the typical course of treatment.
   b. A warning that the device should not be used near an open flame, high heat or electric cautery devices.
   c. A warning regarding the risk of frostbite or burns if device is not used as directed.
   d. A warning that if skin irritation persists, discontinue use of the product.
   e. A warning that the device should not be used by individuals with known allergies to product ingredients, as use by such individuals may lead to an allergic response including difficulty breathing
   f. A warning that the device should not be directly inhaled, as this may be harmful or fatal.

3. **Please discuss whether you agree with FDA's proposed classification of Class II with special controls for vapocoolant devices. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**