FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

24 Hour Summary
Neurological Devices Panel
Advisory Committee Meeting
June 3-4, 2021

Introduction

A meeting of the Neurological Devices Panel ("the Panel") of the Medical Devices Advisory Committee was convened on June 3-4, 2021, to discuss and make recommendations related to classification of six unclassified, preamendments device types.

On June 3, 2021 ("Day 1"), in Session I, the Panel discussed and made recommendations regarding the classification of vapocoolant devices, which are currently unclassified preamendment devices, to class II (general and special controls). In Session II, the Panel discussed and made recommendations regarding the classification of acupressure devices, which are currently unclassified preamendment devices, to class I (general controls). In Session III, the Panel discussed and made recommendations regarding the classification of electro-acupuncture stimulators, which are currently unclassified preamendment devices, to class II (general and special controls).

On June 4, 2021 ("Day 2"), in Session I, the Panel discussed and made recommendations regarding the classification of attention task performance recorders, which are currently unclassified preamendment devices, to class II (general and special controls). In Session II, the Panel discussed and made recommendations regarding the classification of optical contour sensing devices, which are currently unclassified preamendment devices, to class I (general controls). In Session III, the Panel discussed and made recommendations regarding the classification of plunger-like joint manipulators, which are currently unclassified preamendment devices, to class II (general and special controls).

Panel Discussion and Recommendations

Day 1

Session I

The Panel discussed the following FDA-identified risks to health for vapocoolant devices:

- Pain or discomfort
- Skin irritation
- Thermal injury
- Electrical shock or burn

- Interference with other devices
- Device failure/malfunction leading to ineffective treatment
- Asthma
- Hallucination

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of vapocoolant devices under product code "MLY". The Panel also expressed concerns with the risk of abuse/addiction and flammability.

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed with the identified special controls as proposed. The Panel also recommended:

- Controls to mitigate the risk of abuse, including requiring a prescription, restricting sales, product tracking, a warning in the labeling about potential death if inhaled, and chemical additives to deter abuse (e.g., unattractive odor);
- Limiting use on oral mucosa and in patients with diabetes, open wounds, or wound healing complications;
- Shelf life testing to mitigate device contamination;
- Performance testing to mitigate device failure; and
- Including dose and duration of treatment in the labeling.

The Panel unanimously agreed with the FDA's proposed classification of class II (special controls) for vapocoolant devices.

Session II

The Panel discussed the following FDA-identified risks to health for acupressure devices:

- Pain or discomfort
- Skin irritation

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of acupressure devices under product code "MLY", and generally considered the device type to be low risk. Correct placement of the device was deemed the most important safety concern. Several Panelists also expressed concerns with the limited evidence in support of device effectiveness.

The Panel generally agreed with the FDA's proposed classification of class I (general controls), but suggested the labeling include a warning stating the device provides no/limited effectiveness.

Session III

The Panel discussed the following FDA-identified risks to health for electro-acupuncture stimulators:

- Adverse tissue reaction
- Infection
- Patient injury or discomfort including:

- Electrical shock or burn
- Bleeding
- User error

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of electro-acupuncture stimulators under product code "BWK". In addition, the Panel identified the risk of death, based on a single, outside of the U.S. (OUS) case series published in 1981, in which three (3) patients diagnosed with schizophrenia died after needle perforation of internal organs. The Panel also expressed concerns with the migration of needles into deeper muscle tissue during stimulation (especially when using textured needles), as well as the risk of micro-shocks and sterility of the device components.

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed that the identified proposed special controls adequately covered the risks and safety concerns discussed. The Panel also recommended:

- Labeling statements regarding the potential for improper use to result in organ injury and death; and
- Identification in the labeling of needles/components that are compatible with the device.

Many Panelists concluded that the available evidence demonstrates electro-acupuncutre stimulators are not effective, with some stating these devices should not continue to be marketed. In conjunction with the potential for death, which some considered an unreasonable risk of injury, many Panelists disagreed with the FDA's proposed classification of class II (special controls) and instead recommended the device type be classified into class III (premarket approval). Other Panelists acknowledged the lack of effectiveness data but believed special controls could mitigate the risks to health and therefore agreed that the device type could be classified into class II (special controls).

Day 2

Session I

The Panel discussed the following FDA-identified risks to health for attention task performance recorders, when intended to measure reaction time and associated patient performance in response to attention tasks, without aiding in assessment or diagnosis:

- Patient discomfort (e.g., visual or mental fatigue)
- Incorrect or inaccurate measurements of reaction time or other attention tasks

The Panel also discussed the following FDA-identified risks to health for attention task performance recorders, when intended to aid in assessment or diagnosis of specific diseases or conditions (e.g., attention deficit hyperactivity disorder (ADHD)):

- Patient discomfort (e.g., visual or mental fatigue)

- Incorrect or inaccurate results leading to inaccurate assessment or delayed diagnosis, both of which could result in inappropriate therapy or delay in treatment

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of attention task performance recorders under product code "LQD". The Panel also identified the potential breach of confidentiality of patient data inputted into the device, financial burden of care on parents/caregivers, and the patients'/caregivers' lack of knowledge of limited device effectiveness as risks; these comments apply to both intended uses.

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed with the identified special controls as proposed. The Panel also recommended:

- Controls to protect confidentiality/privacy of patient data;
- Labeling statements regarding the potential risk of visual stimulation inducing seizures in epileptic patients; and
- If possible, controls to ensure adequate informed consent of patients and caregivers regarding the limited effectiveness of the device.

The Panel unanimously agreed with the FDA's proposed classification of class II (special controls) for attention task performance recorders for all intended uses.

<u>Session II</u>

The Panel discussed the following FDA-identified risks to health for optical contour sensing devices:

- Device failure/malfunction leading to inaccurate results and diagnosis
- Use error leading to inaccurate results and diagnosis

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of optical contour sensing devices under product code "LDK". The Panel also identified the risk of potential breach of confidentiality of patient data inputted into the device.

Some Panelists questioned the effectiveness of this device type in diagnosing spinal deformities (e.g., scoliosis), and noted that LDK devices should not replace the standard of care for diagnosing spinal deformities. However, there was general agreement that the device is low risk. When used for monitoring the progression of treatments for spinal deformities, the device type also reduces the need for follow-up X-rays and therefore decreases radiation exposure.

The Panel unanimously agreed with the FDA's proposed classification of class I (general controls) for option contour sensing devices.

Session III

The Panel discussed the following FDA-identified risks to health for plunger-like joint manipulators:

- Adverse tissue reaction
- Electric shock or burn
- Pain
- Discomfort
- Tissue injury

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of plunger-like joint manipulators under product code "LXM". In addition, the Panel identified several serious risks reported in the literature, including vascular injury (e.g., vertebral artery dissection), spinal cord injury, stroke, paralysis, and death. For these reasons, some Panelists recommended contraindicating these devices in the cervical spine and adding explicit warnings of these risks in the labeling. However, some Panelists noted that there is uncertainty surrounding the direct cause and incidence of these adverse events. Manual manipulation of the vertebrae alone may have been the cause in some cases.

The Panel generally agreed that there is a lack of valid scientific evidence to support the safety and effectiveness of plunger-like joint manipulators. The majority of the published articles described studies of these devices in combination with other manuevers and/or manual manipulation, which prevents a direct assessment of these devices for the cleared indications for use. Combined with the identified serious risks to health, the Panel unanimously recommended that plunger-like joint manipulators be classified into class III (premarket approval).

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