Classification of Electro-Acupuncture Stimulators
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 electro-acupuncture stimulators:

Identified Risk	**Description/Examples**
Adverse tissue reaction	• Skin irritation • Local pain • Changes in skin pigmentation such as hematoma and skin pallor
Infection	• Infection due to non-sterile/contaminated needle and other types electrodes that enters epidermis or deeper layer of the skin • Sepsis
Patient injury or discomfort: including: • electrical shock or burn • bleeding	• Excessive trauma, perforation of blood vessels and organs caused by needles leading to bleeding, ecchymosis, hematoma • Electrical shock or burn • Muscle cramping
Use error	• User discomfort, tissue injury, or delayed treatment

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

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 electro-acupuncture stimulators. 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 electro-acupuncture stimulators under product code "BWK"

Identified Risk	**Recommended Mitigation Measure**
Adverse tissue reaction	• Biocompatibility evaluation • Labeling
Infection	• Sterilization validation • Cleaning validation • Shelf life testing • Labeling
Patient injury or discomfort: including: • electrical shock or burn • bleeding	• Electrical, mechanical, and thermal safety testing • Electromagnetic compatibility (EMC) testing • Non-clinical performance testing • Software validation, verification, and hazard analysis • Labeling
User error	• Labeling

Please discuss whether the identified special controls for electro-acupuncture stimulators appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Performance testing must demonstrate the sterility of device components that are provided sterile.
3. Performance testing must demonstrate continued sterility, package integrity, and device functionality over the labeled shelf life for device components provided sterile.
4. Performance testing must validate cleaning procedures and demonstrate continued device functionality over the labeled shelf life for reusable patient-contacting components.
5. Performance testing must demonstrate electromagnetic compatibility and electrical, mechanical and thermal safety in the intended use environment.
6. Non-clinical performance testing of the device and electrodes must be conducted to validate the specified electrical output and duration of stimulation of the device.
7. Software verification, validation, and hazard analysis must be performed.
8. Labeling must include the following:
    a. Instructions for use, including identification and placement of appropriate electrodes, and the typical sensations experienced during treatment;
    b. A warning stating that the device is only for use on clean, intact skin;
    c. A detailed summary of the electrical output and the device technical parameters;
    d. A shelf life for the device and accessories;
    e. A statement that sterile components are intended for single use only; and
    f. Instructions on care and cleaning of the device for reusable components.

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