Classification of Electro-Acupuncture Stimulators Under Product Code “BWK”

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Device Description

- Electro-acupuncture stimulators are designed to function based on a principle of traditional Chinese medicine
  - Stimulation of certain areas of the body (acupuncture points) can have a physiological influence on non-adjacent body parts or organ systems.
- The device applies a low voltage electric current to stimulate these acupuncture points via percutaneous or transcutaneous electrodes.
- Some devices also measure skin conductance to identify acupuncture points by their high conductivity or come with accessory applicators intended to aid in placement of acupuncture needles.

Indications for Use

These devices have been cleared as prescription devices for the following indications for use:

- To be used in the practice of acupuncture
- For pain relief
- Treatment of chronic pain
- Does not have curative value but stimulates appropriate auricular acupuncture points
- Acute Pain: Post–operative pain
- Chronic Pain: Chronic back pain, Cervical syndrome, migraine
- Pain associated with joint disease or primary and secondary neuralgias.

Regulatory History

- Pre-amendment, i.e., marketed prior to May 1976
- Unclassified when marketed
- Currently these devices are being regulated through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are “substantially equivalent” to a legally marketed predicate device. Since these devices are unclassified, there is no regulation associated with the product code.
- To date, the FDA has cleared 21 devices under the BWK product code.

Clinical Background

- Pain: subjective sensation of discomfort caused by either actual or potential injury to the body that can be described in terms of location, intensity, duration, and nature.

- Pathophysiology is complex but can be generally described as painful stimuli arising in the periphery, which are subsequently received by nociceptors which communicate peripheral nociceptive input to the dorsal horn of the spinal column where interneuron modulation occurs as the signals are distributed to other structures of the CNS.

Clinical Background

- Management:
  - Nonpharmacologic
    - Exercise therapy
    - Cognitive behavioral therapy
    - Patient education
    - Mind-body therapies (Mindfulness-based stress reduction)
    - Physical interventions:
      - Physical modalities: (transcutaneous nerve stimulation (TENS), heat, ultrasound etc.)
      - Chiropractic manipulation
      - Massage
      - Acupuncture
      - Trigger point injections and dry needling
  - Pharmacologic
    - NSAIDS, acetaminophen, antidepressants, and anti-epileptic drugs
    - Opioids, if necessary
  - Interventions
    - Muscle or joint injections
    - Neuro-destructive or neuromodulatory procedures

Literature Review

- A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of electro-acupuncture stimulators under product code “BWK”.
- Literature searches were conducted to identify any relevant articles published between January 1, 2010 and December 31, 2020.
- The search was limited to human clinical studies with full text available in English.
- The search yielded 2,953 initial literature references. After duplicate articles were removed, a total of 2,582 articles remained.
- A total of 105 articles were determined to be relevant to the safety and/or effectiveness of electro-acupuncture stimulators.

Literature Review – Safety Assessment

- 28 of the 105 articles reported on device safety
- 17 of these 28 articles reported electro-acupuncture (EA)-related adverse events, including:
  - Mild fainting
  - Ecchymosis
  - Mild hematoma
  - Skin pallor
  - Skin pigmentation
  - Vertigo
  - Nausea
  - Vomiting
  - Chest tightness
  - Unconsciousness
  - Death

Literature Review – Effectiveness Assessment

- 95 of the 105 articles reported on device effectiveness for indications including:
  - Musculoskeletal pain (n=42)
  - Post-operative pain and analgesic reduction (n=17)
  - Neuropathic pain (n=6)
  - Stroke (n=4), Stroke rehabilitation (n=5), Cerebral palsy (n=1), Parkinson's disease (n=3), Cerebral infarction (n=1), Carpal tunnel syndrome (n=2), Fatigue (n=4), Headache/migraine (n=2), Fibromyalgia (n=1), and Motion sickness (n=1)
- Overall, the evidence strongly indicates EA stimulation has a favorable effect on musculoskeletal, post-operative, neuropathic pain, and analgesic reduction compared to sham and control groups (conventional treatment or no treatment).

Literature Review – Summation

- More evidence needed to determine whether the usage of EA stimulation is consistently associated with the AE events reported and whether there is strong evidence of EA stimulation effectiveness in musculoskeletal, post-operative, neuropathic pain, analgesic reduction, and stroke indications.

- There is little published evidence about EA stimulation treatment for stroke rehabilitation, Parkinson's disease, acute cerebral infarction, carpal tunnel syndrome, fatigue, fibromyalgia, and headache.

- All these indications require further study.

Medical Device Reports

- Medical Device Reporting (MDR): the mechanism for the FDA to receive significant medical device adverse events from:
  - mandatory reporters (manufacturers, importers and user facilities)
  - voluntary reporters (health care professionals, patients, consumers)

Medical Device Reports

- MDR reports can be used effectively to:
  - Establish a qualitative snapshot of adverse events for a specific device or device type
  - Detect actual or potential device problems used in a “real world” setting/environment, including:
    - rare, serious, or unexpected adverse events
    - adverse events that occur during long-term device use
    - adverse events associated with vulnerable populations
    - off-label use
    - user error

Medical Device Reports

- Limitations
  - Under reporting of events
  - Potential submission of incomplete, inaccurate, untimely, unverified, or biased data
  - Incidence or prevalence of an event cannot be determined from this reporting system alone
  - Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report
  - MAUDE data does not represent all known safety information for a reported medical device

Medical Device Reports

- MAUDE (Manufacturer And User Facility Device Experience) Database reviewed for product code “BWK” from April 3, 1979 through December 31, 2020:
  - No Medical Device Reports

Recall History

- The Medical Device Recall database contains Medical Device Recalls classified since November 2002.
- Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA.
- The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated.
- FDA recall classification (resulting in the posting date) may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall.

Recall History

- A review of the database found no recalls for devices under the BWK product code.

Risks

- Adverse tissue reaction – This can result from improper cleaning of reusable patient-contacting components or non-biocompatible materials.
- Infection – This can result from non-sterile or contaminated needles and other types of electrodes that enter the epidermis or deeper layers of skin.
- Patient injury or discomfort – This can result from over-stimulation or excessive trauma caused by percutaneous components.
- User error – This can result from inadequate instructions for use labeling.

We believe that special controls, in addition to general controls, can be established to mitigate these risks.

Risks and Mitigations

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

Proposed Classification

882.5889 Electro-acupuncture stimulator.

(a) *Identification.*

An electro-acupuncture stimulator is a prescription device intended for medical purposes, such as pain relief, that is used to apply an electrical current to acupuncture points through electrodes in the practice of acupuncture by a qualified practitioner of acupuncture therapy.

(b) *Classification.*

Class II (special controls). The special controls for this device are:

Proposed Special Controls

We propose the following Special Controls for these devices:

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.

Proposed Special Controls

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 applicators and components provided sterile;
    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.

Thank You

Questions to Panel - BWK

Question 1 to Panel

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

Question 1 to Panel

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.

Question 2 to Panel

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
- 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.

Question 2 to Panel

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
    - 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
    - does not present a potential unreasonable risk of illness or injury.

Question 2 to Panel

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.

Question 2 to Panel

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.

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

Question 2 to Panel

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.

Proposed Special Controls

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.

Question 2 to Panel

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.

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 applicators and components provided sterile;
    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.

Question 3 to Panel

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

End of Panel Questions for Product Code “BWK”