Classification of Acupressure Devices Under Product Code "MVV"

Presenter
Mary Keszler, MD
Division of Neuromodulation and Physical Medicine Devices
Office of Health Technology 5-Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

Neurological and Physical Medicine Devices
Advisory Panel Meeting
June 3-4, 2021

Outline

- Device Description
- Indications for Use
- Regulatory History
- Clinical Background
- Literature Review
- Medical Device Reports
- Recall History
- Risks to Health & Mitigations
- Proposed Classification
- FDA Questions

Device Description

- Acupressure devices are used to apply pressure to the Pericardium (P6 or PC6) acupuncture point on the inner wrist. Application of consistent pressure at this point is applied through elastic or via a wrist band, strap, or adhesive strip. A raised wooden or plastic bead or button is often embedded within the band, strap, or strip, which creates a resistive force against the inner wrist. In some devices the amount of pressure can be adjusted.

Indications for Use

These devices have been cleared as over-the-counter devices for the following indications for use:

- For the relief of nausea. Nausea may be experienced due to travel (motion sickness), pregnancy (morning sickness), anesthesia, or chemotherapy.
- For the relief of emetic (nausea and vomiting) symptoms associated with post-operative anesthesia.

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 11 devices under the MVV product code.

Clinical Background

- Nausea: unpleasant sensation of needing to vomit and can occur independently or accompany gastric emesis

- Pathophysiology involves a disturbance of the normal rhythmic three cycle per minute gastric myoelectrical activity controlled by the enteric brain neurons and the autonomic nervous system innervating smooth muscles cells of the GI tract

- Vomiting: reflexive emesis activated by neuronal stimuli responsive to chemoreceptor triggers in the brain. Emesis occurs upon relaxation of the gastric esophageal sphincter, contraction of the proximal small bowel and abdominal muscles.

Clinical Background

- Management:
  - Pharmacotherapy
    - Antiemetics
    - Prokinetics
    - Antidepressants
  - Devices
    - Humanitarian use of gastric electrical stimulation via implanted electrodes
  - Surgery
    - Gastrostomy
    - Pyloroplasty
    - Jejunostomy
    - Gastrectomy

Literature Review

- A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of acupressure devices under product code “MVV”.
- Literature searches were conducted to identify any relevant articles published between January 1, 2010 and December 31, 2020.
- The searches were limited to publications in English and excluded conference proceeding and abstracts.
- The searches yielded 253 initial literature references. After duplicate articles were removed, the literature search of the above electronic databases yielded 202 literature references.
- A total of 28 published literature references were determined to be relevant to the safety and/or effectiveness of acupressure devices.

Literature Review – Safety Assessment

- Five of the 28 articles reported on adverse events
- Reported Adverse Events Include:
  - Redness
  - Swelling
  - Tenderness
  - Bruising
  - Paresthesia
  - Feeling of acupressure wristbands tightness
  - Itchiness
  - Discomfort and pain

Literature Review – Effectiveness Assessment

- Overall, 18 of the 28 (64%) studies reported a statistically significant prevention or reduction in nausea and/or vomiting with use of acupressure wristbands ($p < 0.05$).

Literature Review – Summation

- The adverse events were all mild in nature and resolved after removal of the acupressure wristbands, without additional treatment.
- Clinical evidence from the published literature shows mixed results for the effectiveness of acupressure wristbands in the prevention or reduction of nausea and vomiting.
- Based on the peer-reviewed medical literature, acupressure wristbands are safe and more effective in some patients than others.

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 “MVV” from January 1, 1991 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 only one recall for devices under MVV product code
  - One Class II recall has been identified. A manufacturer's acupressure/acustimulation wrist bands were recalled in 2007 because the firm was marketing their devices before its 510(k) submission received clearance.

Risks

- Pain or discomfort – This can result from bruising, swelling and tenderness under the wrist band and at the pressure point, particularly if applied too tightly.

- Skin irritation – This can result from improper cleaning and from pressure/contact with the wrist band.

- We believe general controls are sufficient to mitigate these risks.

Proposed Classification

890.5872 Acupressure device for nausea

(a) *Identification.*

An acupressure device is used to apply pressure to the Pericardium 6 (P6 or PC6) acupuncture point on the inner wrist(s) for the relief of nausea resulting from motion, pregnancy (morning sickness), post-operative anesthesia, or chemotherapy. Application of consistent pressure at this point is applied through elastic or applied force via a bead or button embedded in a wrist band, strap, or adhesive strip.

(b) *Classification.*

Class I (general controls).

Thank You

Questions to Panel - MVV

Question 1 to Panel

FDA has identified the following risks to health for acupressure devices:

- pain or discomfort
- skin irritation

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of the acupressure devices under product code “MVV”.

In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these acupressure devices.

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 does not believe that special controls will be required for acupressure devices under product code “MVV” and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness for acupressure devices. As such, FDA believes that Class I is the appropriate classification for acupressure devices under product code “MVV.”

Please discuss whether you agree with FDA’s proposed classification of Class I with general controls for acupressure devices under product code “MVV.” 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 “MVV”