

Background Information – Classification of Eyelid Weights

This document contains information for your review and Panel deliberation on the classification of eyelid weights. A description of the device, a draft intended use statement, background information on eyelid weights, guidance information relative to classification of medical devices, and questions for the Panel have been included. If additional information is needed, please contact Ms. Claudine Krawczyk at (301) 594-2053.

A Brief Description of Eyelid Weights:

Eyelid weights are strips of metal, rectangular in shape and spherically contoured to the shape of the eye. They may be adhered to the outer skin of the upper eyelid, or they may be implanted into the upper eyelid.

A Draft Intended Use Statement:

The device is intended for the gravity assisted treatment of the functional defects of lagophthalmos resulting from temporary or permanent facial paralysis, specifically of the orbicularis oculi muscle.

Background Information on Eyelid Weights:

FDA has regulated eyelid weights as devices requiring premarket notification [510(k)]. Five eyelid weights have been cleared to date through the premarket notification process. The devices currently on the market were determined to be substantially equivalent to devices that were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. No standards or guidance have been developed for these devices.

Historically, the premarket notifications have contained descriptive information for the eyelid weight, draft labeling, and literature references supporting the safe use of these devices.

Risks associated with the use of these devices are dependent upon the placement of the device. Only minor complications, such as mild eyelid irritation and blepharoptosis, have been associated with the use of external eyelid weights. For the implanted eyelid weights, a partial list of risks associated with use of the device includes infection, implant shifting or repositioning, and extrusion through the eyelid.

Guidance Information Relative to Classification of Medical Devices:

To assist you in your review and recommendation, several articles from the literature pertaining to eyelid weights are included in this packet. Please consider all other literature references that you consider applicable.

Provided below are excerpts from the Code of Federal Regulations for regulatory consideration.

21 CFR 860.3 - Definitions

- Class I devices are subject to general controls authorized by or under sections of the act. Examples of general controls include registration, adulteration, misbranding, notification, records and reports, and general provisions of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls (see class II below) to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.
- Class II devices are subject to special controls as well as general controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions deemed necessary to provide assurance of safety and effectiveness.
- Class III devices are those devices for which premarket approval is required. A device is in class III if insufficient information exists to determine that general controls or special controls are sufficient to provide reasonable assurance of safety and effectiveness of the device and if, in addition, the device is life supporting or life sustaining, or for a use that is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

21 CFR 886.9 – Limitations of exemptions from section 510(k) of the act

The exemption from the requirement of premarket notification for a generic type of class I or II device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. A sponsor of a class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

- The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; or
- The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; or
- For class II devices, the device is a certain type of in vitro device [see 21 CFR 886.9(b)(3)].

In addition, the “General Devices Classification Questionnaire” and “Supplemental Data Sheet” have been attached.