

Reclassification Petition for lubricating/cleaning solution for artificial eyes

Background:

The citizen's petition to classify this device was submitted with an expectation that FDA would reclassify this device into Class II. The only approved product for this intended use was originally regulated by the Center for Drug Evaluation and Research (CDER). The new drug application for Alcon's Enuclene[®] was originally submitted to FDA in April 1964. It was transferred from CDER to the Center for Devices and Radiological Health (CDRH) in March 1997. Since this device was previously regulated as a drug, it was automatically handled as a Class III medical device under the transitional medical device section 520(l) of the Food Drug and Cosmetic Act (the act).

The intended use for this type of device is to lubricate, clean and wet the artificial eye thereby increasing the wearing comfort to the patient.

The lubricating/cleaning solution is an accessory to the Class I device "artificial eye" described in 21 CFR 886.3200 as "a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or in the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted."

Health and Safety Concerns:

The health and safety risks associated with this device are similar to those of contact lens lubricating and rewetting solutions. One major difference is that the ocular concerns related to the cornea and bulbar conjunctiva present in the contact lens devices are not at present for individuals with a prosthetic eye. However, there still are issues related to the palpebral conjunctiva lining the eyelids and eyesocket.

Toxicology

- The biocompatibility issue is present due to the concern for conjunctival reactions such as giant papillary conjunctivitis (GPC) which can develop in the prosthetic patient.
- Suitability of the plastic container for ophthalmic use is another issue that has been assessed in these types of products intended for instillation onto the ocular conjunctiva.

Microbiology

- Infection of the eye socket is an issue that has been addressed by incorporating a preservative into the currently approved product. Sale of the product as sterile and expiration dating are other methods that have been used to address this concern.

Chemistry

- Stability of the preservative during the labeled expiration date is an issue that has been addressed through shelf life testing of ocular lubricating devices. As described in the May 1, 1997 Guidance for Industry, Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products (Care Products 510(k) Guidance), a preparation labeled for use with contact lenses that contains an ophthalmic demulcent as listed in 21 CFR 349.12 of contact lens lubricating devices will qualify as a lubricating drop. Formulations that lack a demulcent qualify as rewetting drops, but not as lubricating drops.
- Surfactants are commonly used as cleaning agents in contact lens care products.
- There are no pharmacological stability issues for these products as devices since the intended effect is achieved through physical methods and not chemical means. Therefore, the bioavailability of an active ingredient does not enter the picture.

Clinical

- The necessity of conducting clinical tests for a device intended for use with prosthetic eyes is an issue that has not been addressed from a device standpoint. The guidance for the parallel situation of lubricating and re-wetting solutions for use with contact lenses does recommend a 1 month clinical test on a 30 subjects for preparations with the same active ingredient. For formulations with different active ingredients than currently approved for that use, a 3 month study of 60 subjects is recommended to help determine substantial equivalency. Those recommendations help address the interaction of the solution with a contact lens worn over a normal, clear functioning cornea.
- The assessment of biocompatibility and suitability for use with an eye socket lined with conjunctiva may result in a different recommendation or rely primarily on a pre-clinical assessment.

Labeling

- Tamper resistant statements and packaging are present and would apply to any device.
- Appropriate directions, contraindications, warnings and cautions and description of device are present and would apply to any device.

Regulatory considerations – 21 CFR 860.3

- Class I devices rely on “general controls” such as registration, adulteration and misbranding, notification, and general provision of the act.
- Class II devices rely on the general controls as well as other controls such as special controls. Special controls may include things such as development and dissemination of guidelines,

performance standards, postmarket surveillance, patient registries or other appropriate actions deemed necessary to provide assurance of safety and effectiveness.

- Class III devices are generally those where insufficient information exists to determine that general controls or special controls provide reasonable assurance of safety and effectiveness of the device. These device may be the life supporting or life sustaining, or for a use that is of substantial importance in preventing impairment of human health. These devices may present a potential increased level of risk of illness or injury associated with their use.

Note: the term “performance standard” has a very specific regulatory meaning. Part 21 CFR 86.1 is the regulation that defines the purpose and scope of these unique standards. The specific process for development of the standard as well as the required contents is listed in that part. These standards should not be confused with consensus standards developed by standards organization such as ANSI, ISO, ASTM and others. Although performance standards are described in the regulations, they have rarely used for Class II devices. Other types of special controls such as guidance documents are commonly applied to Class II devices.