Classification of Ophthalmic Dispensers
FDA Questions

Ophthalmic Devices Panel of the Medical Devices Advisory Committee November 10, 2022

1. FDA has identified the following risks to health for an ophthalmic dispenser:

Identified Risk	**Description/Examples**
Infection	• This can result from a new device that has microbial contamination as packaged or a device that becomes microbially contaminated because it is improperly cleaned and re-used. • This can result from the microbial contamination of the ophthalmic dispenser and ophthalmic medication because the dispenser tip has touched the eye or touched another unintended surface.
Adverse tissue reaction	• This can result from the use of device materials that are not biocompatible. • This can result from the interaction between the device and ophthalmic medication (for example, chemicals from the device leach into the ophthalmic medication).
Compromised treatment	• This can result from a damaged or defective device. • This can result from inadequate instructions and the device not being used as intended. • Design of dispenser may cause incorrect dosage of medication to be dispensed to the patient.
Mechanical Injury	• This can result from unintended direct physical contact of the eye with the device.

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

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 and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, AND

    - if the device is purported or represented to be for use in supporting or sustaining human life, 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 does not believe that special controls will be required for ophthalmic dispensers under product code "LXQ" and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness for ophthalmic dispensers. As such, FDA believes that Class I is the appropriate classification for ophthalmic dispensers under product code "LXQ."

    Please discuss whether you agree with FDA's proposed classification of Class I for ophthalmic dispensers under the product code "LXQ." If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.