

Bringing Healthy Vision to Everyone, Every Day

CONTACT LENSES & MEDICAL DEVICES – FDA CLASSIFICATION

Contact lenses have been recognized by the U.S. Food and Drug Administration (FDA) as **Class II and Class III medical devices** since 1976.

While regular-wear contact lenses pose a moderate risk to patient health and are classified as Class II medical devices, lenses that can be worn overnight or on an extended-wear schedule are Class III devices because they pose a higher risk to patient health when worn without appropriate physician oversight.

By law, consumers are required to have a valid prescription from an eye care professional to purchase lenses.

DEVELOPING MEDICAL DEVICE STANDARDS TO KEEP PATIENTS SAFE

Congress passed the *Medical Device Amendments (MDA) of 1976* to address the growing need for a review process for medical devices, including contact lenses.

Enactment of MDA was a landmark development in fulfilling FDA's mission to ensure the safety and effectiveness of drugs and devices available to patients.

MDA established a number of minimum requirements and directed FDA to classify all medical devices into one of three classes based on patient risk.

SUPPORTING THE SAFETY & EFFECTIVENESS OF CONTACT LENSES

As JJVCI continues to research and innovate new ways to promote the vision health of patients across the country, maintaining contact lenses' current medical device classification will help support the safety and effectiveness of contact lenses.

MEDICAL DEVICE CLASSIFICATIONS

CLASS I DEVICES

- Pose the lowest risk of injury to patients
- Require a minimum level of FDA regulation to provide reasonable assurance of safety and effectiveness

Class I devices include elastic bandages, examination gloves, and visual acuity charts.



CLASS II DEVICES

- Pose a moderate risk to patients
- Require additional regulation to provide reasonable assurance of safety and effectiveness, such as labeling and post-market surveillance

Class II devices include infusion pumps, hearing aids, and daily wear contact lenses.



CLASS III DEVICES

- Life-supporting or life-sustaining devices
- Pose a higher risk of illness or injury
- Subject to premarket approval and increased regulation aimed at ensuring their safety and effectiveness

Class III devices include certain dental implants, heart valves, and extended-wear contact lenses.

