

Eye Contact

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I got glasses when I was in the first grade. While they made me look nerdy, I had to wear them to see.

When I got to fifth grade, however, I got new glasses with transition lenses, meaning my regular glasses turned into sunglasses when I stepped outside. I thought I was going to look exactly like Tom Cruise in his shades in the movie 'Risky Business.' Sadly, I was wrong. Somehow, they made me look even nerdier.

When I got to high school, I finally got contact lenses. Thankfully my glasses didn't make me look dorky anymore; the tightly rolled cuffs on my jeans took care of that.

Well if I'm feeling nostalgic, Acuvue is making new contact lenses that will let me be cool and nerdy at the same time.

Johnson & Johnson Vision Care, Inc. was just given clearance by the U.S. Food and Drug Administration to market the Acuvue Oasys Contact Lenses with Transitions Light Intelligent Technology. The first of their kind, these are soft contact lenses containing an additive that automatically darkens the lens when exposed to bright light. So it'll be like wearing sunglasses without wearing sunglasses.

Johnson & Johnson hopes to begin selling them about a year from now to the more than 40 million Americans who wear contact lenses, as estimated by the Centers for Disease Control and Prevention.

According to Dr. Xiao-Yu Song, head of research and development for Johnson & Johnson Vision, developing the lenses took more than a decade and involved "numerous clinical trials involving more than 1,000 patients." As part of the approval process, the FDA reviewed scientific evidence, including a clinical study of 24 patients that evaluated daytime and nighttime driving performance while wearing the contact lenses. The study revealed no evidence of concerns with either driving performance or vision while wearing the lenses.

Johnson & Johnson obtained FDA approval for the lenses through a process called the premarket notification 510(k) pathway. Such a request is submitted by manufacturers for new products that are substantially equivalent to an already legally marketed "predicate device." A predicate device is one that is intended for human use and has already been deemed by the FDA to be safe and effective.

So Johnson & Johnson simply had to demonstrate to the FDA that despite the transition additive, their new lenses were substantially equivalent to existing contact lenses. If traditional contact lenses were not considered a predicate device, or if the new transition lenses were substantially different, Johnson & Johnson would have been forced to go through the premarket approval process.

This process involves scientific and regulatory review of certain medical devices to evaluate their safety and effectiveness. These medical devices support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The premarket approval process is the most stringent application required by FDA. The applicant must receive FDA approval prior to marketing their device.

The FDA warned that the contacts are intended for daily wear for up to 14 days, should not be worn while sleeping, nor be exposed to water. The agency also cautioned that the lenses should not be used as substitutes for UV protective eyewear.

I think I'll stick with old-fashioned sunglasses. I'll even wear them at night – after all, the sun never sets on the cool.

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