

Center for Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

October 21, 2020

To whom it may concern:

My name is Dr. Paul Karpecki. I am an optometrist and have been practicing for over 25 years. I serve as the director of cornea services at the Kentucky Eye Institute in Lexington KY and an Associate Professor at the Kentucky College of Optometry. I have been an educator for the profession including the current Chief Medical Editor for our most read journal, Review of Optometry. I am a member of the American Academy of Optometry, the AOA, the KOA, IOA and am board certified. I have been teaching about presbyopia correction since the late 1990s at numerous conferences— at least 20-30 per year and in various publications.

I have been watching the VisAbility technology since inception and am excited about where it would fit into practices and how it would benefit patients. We have not had a viable option to correct patients who reach the age of presbyopia and loss of near vision is one of, if not the most common complaint optometrists hear on a daily basis.

Optometry has responded positively to learning about the VisAbility technology through lectures and publications. I believe the acceptance is due to the fact that the clinical trial data is showing excellent results combined with a procedure that does not involve the visual axis of the eye. They have shown a willingness to support this procedure as a recommendation due to the safety data, to provide follow-up care of these patients in post-operative management, conduct testing and vision measurements, monitor and address healing and recovery.

The VisAbility technology is the first technology that addresses patients' needs for presbyopia without compromising distance vision or inducing any unwanted adverse events like haloes or glare. The only current options for a patient with presbyopia include spectacle lenses (bifocal, trifocal and progressive), multifocal contact lenses and mono vision contact lenses. All these options have limitations. There are patients that cannot adjust to bifocal, trifocal or progressive lenses. Because of the age of these patients contact lenses have challenges and a low success rate. The multifocality of various existing technologies results in splitting light and patients experience halos and glare. Surgical options such as multifocal intraocular lenses can result in halos and glare as well and 99% of the time are limited to patients with cataracts, which is around ages 65-75, far beyond the age of when patients experience presbyopia issues.

The benefit to patients with the VisAbility implant is significant. Many of my patients have been waiting for this technology and frequently share their frustration with other modalities for correcting presbyopia. The safety of the technology is unprecedented as it doesn't involve implants or inlays in the visual axis or light splitting IOLs that can have unwanted side effects. This technology purely focuses on the natural mechanism for accommodation via the zonules and crystalline lens flexing. It targets the cause of presbyopia, not a replacement of some other structure or an addition that cannot help at all distances or affect our accommodative mechanism. This is the first technology to do so.

This technology would be used by patients over age 45 who have not adapted to other corrective options such as spectacles or contact lenses and those whose life tasks demand near and distance vision that works seamlessly, like our eyes had previously.

What I have seen in patients before and after the procedure is restoration of the accommodative system allowing them to maintain distance vision (without compromise) and return their near and intermediate vision. The results are the most impressive I have witnessed in my career for the correction of presbyopia. No other technology or modality from surgery to contact lenses and spectacles has achieved what this technology has shown in US FDA clinical studies. It has allowed patients to return to normalcy, the ability to function at their highest levels and a significant positive impact on quality of life—all without compromise to vision. This is indeed a rare discovery and one that will benefit society greatly.

Regards

A handwritten signature in black ink, appearing to read "Paul Karpecki". The signature is fluid and cursive, with a large initial "P" and a long, sweeping underline.

Paul Karpecki, OD  
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