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FDA approves RxSight's light adjustable lens

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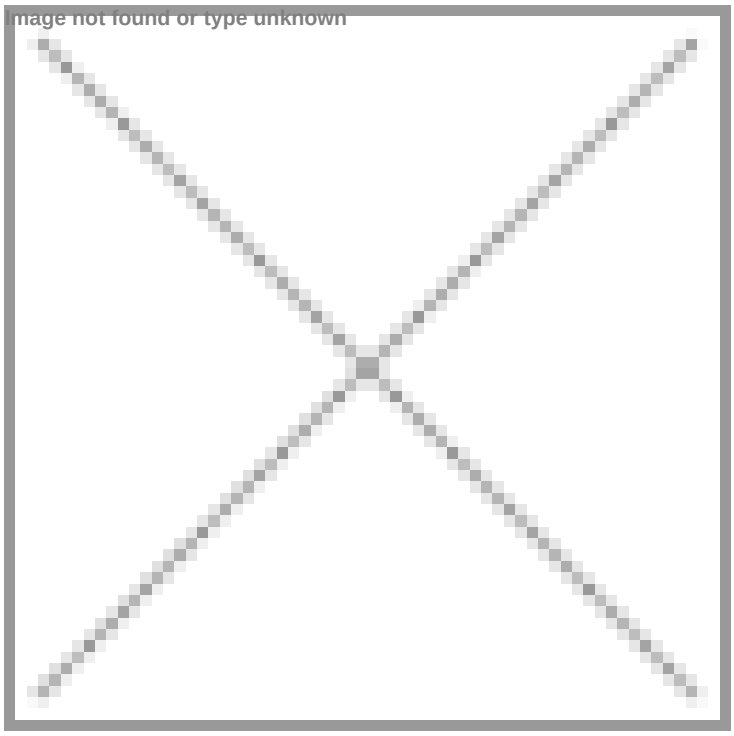
RxSight has also received its CE mark for an expanded cylinder range.



Singapore – RxSight (a US based medical devices company) announced that the U.S. Food and Drug Administration (FDA) has approved the RxSight Light Adjustable Lens and the Light Delivery Device (LDD) for patients with pre-existing astigmatism of ? 0.75 diopters undergoing cataract surgery. This action ushers in a new era in the treatment of cataracts, as RxSight's Light Adjustable Lens is the first and only FDA approved intraocular lens (IOL) that can be adjusted post-operatively to improve uncorrected visual acuity.

"Predictable and accurate refractive outcomes are essential to ensure patients are happy with their vision following cataract surgery," said Vance Thompson, M.D. of Vance Thompson Vision in Sioux Falls, SD. "Until my work as an investigator in the Phase III study of the Light Adjustable Lens, I had never encountered an IOL that consistently delivered the refractive accuracy that my premium cataract patients demand."

Dr. Thompson continued, "Unfortunately, no matter what we do preoperatively with our measurements and mathematical calculations, the implant power is rarely perfect because of the variables of incision healing and the final effective lens position. With the Light Adjustable Lens, we can address these limitations for the first time ever and more predictably deliver the results patients desire. Light adjustable implants will change the way we do cataract surgery forever, and I am thrilled that I will be able to finally deliver this level of care to my patients."

FDA approval was based on results of a U.S. randomized, pivotal study comparing the Light Adjustable Lens to a commercially available monofocal lens in 600 patients with pre-existing astigmatism at 17 investigational sites. Patients receiving the Light Adjustable Lens, followed by light treatment with the LDD, achieved UCVA of 20/20 or better at six months postoperatively at approximately twice the rate of patients receiving a monofocal lens.

RxSight has also received its CE mark for an expanded cylinder range (-0.5 to -3.00 diopters).