

OptiMedica laser system gets 510(k) clearance

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Santa Clara, CA—A proprietary laser system that combines a femtosecond laser, integrated optical coherence tomography (OCT) imaging, and a proprietary pattern scanning technology (Catalys Precision Laser System, OptiMedica) has received FDA 510(k) market clearance for capsulotomy and lens fragmentation.

“The FDA approval of [the laser system] is an exciting development in the emerging field of laser cataract surgery and a key milestone in the history of OptiMedica,” said Mark J. Forchette, OptiMedica president and chief executive officer. “OptiMedica has been committed to defining and delivering the standard for precision and accuracy in laser cataract surgery since the day our company was founded. We are proud to introduce the industry’s most sophisticated laser cataract surgery system to U.S. patients and physicians.”

According to OptiMedica, the laser system was designed to deliver the precision and safety benefits of femtosecond laser to cataract surgery. It features a patient-docking interface designed to provide a stable, comfortable dock and a clear optical path for the OCT and laser. It also provides an image-guidance system that identifies ocular surfaces and establishes safety zones, allowing a physician to customize the treatment and ensuring that the laser pulses are delivered precisely to the intended location.

“[The laser system] is a sophisticated, yet simple-to-use device that delivers unequalled precision and is, quite frankly, the most well-designed medical product I have ever seen,” said William J. Culbertson, MD, professor of ophthalmology and holder of the Lou Higgins Distinguished Chair in Ophthalmology at the Bascom Palmer Eye Institute, Miller School of Medicine, University of Miami. “My colleagues and I have been fortunate to have access to the [proprietary] technology for years, and we firmly believe it will revolutionize cataract surgery.”