

OptiMedica Receives FDA Market Clearance of the Catalys™ Precision Laser System

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FOR IMMEDIATE RELEASE

SANTA CLARA, Calif. — December 22, 2011— Global ophthalmic company OptiMedica Corp. has announced the U.S. Food and Drug Administration (FDA) 510(k) market clearance of its Catalys Precision Laser System, a next generation laser cataract surgery system that brings unequaled precision and accuracy and a markedly streamlined workflow to the laser cataract procedure. Catalys combines a femtosecond laser, integrated Optical Coherence Tomography (OCT) imaging and OptiMedica's breakthrough pattern scanning technology in an ergonomic, easy-to-use system that allows cataract surgeons to perform image-guided pre-operative laser lens conditioning. The system is FDA cleared for capsulotomy (a circular incision in the lens capsule) and/or lens fragmentation (segmenting and softening of the lens to prepare for removal).

"The FDA market clearance of Catalys 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. I want to commend our team on this important achievement."

Catalys is the product of an extensive effort by OptiMedica to deliver the precision and safety benefits of femtosecond laser to cataract surgery, a widely performed procedure estimated at 19 million cases worldwide per year.¹ One of the most important steps during laser cataract surgery is creating the capsulotomy, as its size, shape, and positioning may be key determinants for effective lens position.² In fact, a deviation of just 0.5 mm from the intended effective lens position has been shown to result in 1.00 diopters of refractive error.³

Clinical study results published in the peer-reviewed *Journal of Cataract & Refractive Surgery* have demonstrated that Catalys delivers unequaled precision and accuracy, producing capsulotomies that are within 30 microns of intended size and 80 microns of intended center, with near perfect circularity.⁴ Laser lens fragmentation with Catalys has also been shown to greatly improve the ease of lens disassembly, reducing cumulative dissipated energy (CDE) during ultrasound phacoemulsification by approximately 40 percent.⁵

"The product of years of development and refinement, Catalys is a sophisticated yet simple-to-use device that delivers unequaled precision and is, quite frankly, the most well designed medical product I have ever seen," said William J. Culbertson, M.D., Professor of Ophthalmology, The Lou Higgins Distinguished Chair in Ophthalmology, Bascom Palmer Eye

Institute, Miller School of Medicine, University of Miami. “My colleagues and I have been fortunate to have access to the Catalys technology for years, and we firmly believe it will revolutionize cataract surgery.”

OptiMedica developed the Catalys system in close collaboration with a Medical Advisory Board of cataract experts from around the world, with the shared objective to deliver unprecedented accuracy, an exceptional experience and a seamless fit into surgical center workflow. Key innovations reflecting this objective include a Liquid Optics™ Interface that ensures stable system-patient attachment and optimizes the optical path to the patient’s eye, and a proprietary Integral Guidance™ system that ensures the femtosecond laser pulses are delivered safely and precisely to the intended location. In addition, the system features an easy-to-use and elegant graphical user interface designed to simplify the planning process and minimize the time the patient is under the dock.

Catalys was CE mark approved in August 2011 and has since been shipped to leading ophthalmic centers outside the United States.

About OptiMedica

Founded in 2004 and headquartered in Santa Clara, Calif., OptiMedica Corp. is a Silicon Valley-based global ophthalmic device company dedicated to developing performance-driven technologies that improve patient outcomes. Exclusively focused in the cataract therapeutic area, the company has developed the Catalys Precision Laser System to deliver unparalleled precision in cataract surgery through image-guided pre-operative lens conditioning. Catalys is U.S. Food and Drug Administration 510(k) cleared for market and CE mark approved for performing capsulotomy and/or lens fragmentation during cataract procedures.

OptiMedica’s legacy of innovation in ophthalmology also includes the development and commercialization of the PASCAL® Method of retinal photocoagulation, which was acquired by Topcon Corp. in August 2010. The company is funded by Kleiner Perkins Caufield & Byers, Alloy Ventures, DAG Ventures, BlackRock Private Equity Partners and Bio*One Capital. For more information, please visit www.optimedica.com.

References

¹ 2011 Market Scope Report on the Global Cataract Equipment Market

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⁴ Friedman, NJ, et al., “Femtosecond Laser Capsulotomy,” *Journal of Cataract & Refractive Surgery*, 2011 July; 37(7): 1189-1198.

⁵ Palanker, D., et al., “Femtosecond Laser-Assisted Cataract Surgery with Integrated Optical Coherence Tomography,” *Science Translational Medicine*, Vol 2 Issue 58: 1-9 (2010).

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