

NAVILAS® Laser System Earns FDA Approval

(Dallas, Texas, Nov 2, 2009) OD-OS announces that it has earned FDA 510k Clearance to market [NAVILAS®](#), its product for retina laser therapy. The new navigated laser system incorporates advanced imaging with retinal laser therapy in a planned and controlled way using image registration in one device with integrated workflow to improve the safety, accuracy, speed, comfort and transparency of retina laser photocoagulation. Laser photocoagulation is the current standard in the treatment of many retinal disorders including Diabetic Retinopathy and Diabetic Macular Edema (DME).

NAVILAS®, allows physicians to move beyond conventional slit lamp based photocoagulation that provides only a partial slit image of the retina. The NAVILAS® system produces a live image of the fundus in true color, IR and red-free as well as fluorescein angiography (FA) with 50 degree field of view on a monitor - panable across the fundus. In contrast to fundus cameras or scanning laser ophthalmoscopes, this patented imaging technology is capable of real-time imaging of the retina in color - both mydratic and non-mydratic - while including a treatment laser to treat the retina.

“In trials, initial accuracy results with NAVILAS® indicate a microaneurysm hit rate of 92% as evidenced by post treatment color overlay photographs,” reported William Freeman, M.D., Professor and Director of the Jacobs Retina Center at the UCSD Shiley Eye Center, La Jolla, CA, during his presentation at Retina Subspecialty Day of the AAO 2009 in San Francisco..

With NAVILAS®, doctors have freedom of neck movement and are able to adjust their height and proximity to the patient for maximum ergonomic benefits. “The neck and back strain of slit lamp examination will be greatly reduced,” said Dr. Michael Ober, Retina Consultants of Michigan, Southfield Michigan.

NAVILAS® made its first appearances in the US in New York in September at the Retina Congress and last week at the American Academy of Ophthalmology in San Francisco. “In both venues, doctors were excited by the new technology that will, for the first time, allow them to use what we call Retina Navigation, the ability to IMAGE - PLAN - TREAT and DOCUMENT retina disorders,” said Winfried Teiwes, CEO.

For more information on the NAVILAS® system, call (877) 628-6367 or visit www.od-os.com.

About OD-OS

[OD-OS](http://www.od-os.com) is an ISO 9001 and ISO 13485 certified medical device company headquartered in Teltow/Berlin, Germany. Its US operation, responsible for marketing, sales and support, is located Grapevine/Dallas, Texas.

OD-OS is a subsidiary of SensoMotoric Instruments (SMI), the technology leader in eye tracking and registration solutions for refractive laser surgery. Over the past 15 years, SMI has supplied technology to most major refractive laser manufacturers.

In 2008, after more than 4 years of development creating Retina Navigation within SMI, the core development team was spun-out into OD-OS and charged with resources and ophthalmic industry experts to bring Retina Navigation with its first product, NAVILAS, to the market. For more information visit www.od-os.com or in the US call 1 (877) 628-6367 or Europe at +49 (3328) 31 282-100.

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Photos and interviews available upon request

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