

## **OmniGuide Announces FDA 510K Clearance of the OmniGuide BeamPath CO<sub>2</sub> Mark I Laser Beam Delivery System**

Cambridge, MA – May 16, 2005 – OmniGuide Inc., ([www.Omni-Guide.com](http://www.Omni-Guide.com)) today announced the FDA 510K clearance of the OmniGuide BeamPath CO<sub>2</sub> Mark I Laser Beam Delivery System, enabling flexible fiber delivery of a CO<sub>2</sub> laser for minimally invasive surgery. To the best of the company's knowledge, this is the first ever FDA clearance for photonic bandgap technology in a surgical system. The system is cleared for multiple indications including incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in the medical specialties of general and plastic surgery, oral / maxillofacial surgery, dentistry, dermatology, endoscopic and open surgical procedures related to gynecology, otorhinolaryngology, gastroenterology, neurosurgery, and pulmonary surgery for surgical and aesthetic applications.

"The FDA clearance of our flexible fiber delivery system for CO<sub>2</sub> lasers is a huge step forward for our core medical business," said Dr. Steve Sheng, President and Chief Executive Officer of OmniGuide. "This is the first step in establishing a diversified medical product portfolio based on OmniGuide's revolutionary fiber technology. The clearance will allow OmniGuide to fully engage the human surgical market and drive new minimally invasive treatment modalities in multiple specialties."

The OmniGuide BeamPath CO<sub>2</sub> Mark I Laser Beam Delivery System enables flexible delivery of CO<sub>2</sub> laser light through flexible or rigid endoscopes. The CO<sub>2</sub> laser has been used for surgical procedures for over 30 years. The CO<sub>2</sub> laser wavelength, at 10.6 microns, offers unique tissue interaction characteristics which include highly localized thermal effects, ultra-low and controllable depth of penetration, as well as the ability to coagulate small to medium sized blood vessels. Until now there was no adequate flexible delivery mechanism for CO<sub>2</sub> laser beams. OmniGuide has overcome this challenge by developing a hollow-core fiber based on photonic bandgap technology developed at the Massachusetts Institute of Technology by Prof. Yoel Fink.

OmniGuide has completed a first human treatment on November 19th 2004, using the fiber to treat a patient suffering from an acute case of recurrent respiratory papilloma involving the larynx and the trachea. The treatment was completed based on a compassionate use request. The patient was treated in the office trans-nasally with local anesthesia, demonstrating the ability of OmniGuide's technology to drive new standards of care. OmniGuide's minimally invasive laser technology has already generated significant interest from multiple leading clinical groups in the fields of otolaryngology and head and neck surgery.

Yoel Fink, John Joannopoulos and Edwin Thomas, all faculty members at MIT, and Uri Kolodny, founded OmniGuide in May 2000, in order to commercialize patented research conducted at MIT on omnidirectional reflectors (Temelkuran et al. Nature 420, pp. 650-653 (2002)).

Based in Cambridge MA, where its corporate offices and labs are located, OmniGuide has an exclusive license from MIT on omnidirectional reflectors. The company has raised \$29.5M from Ray Stata, Mukesh Chatter, Alliance Technology Ventures, 3i US, Westbury Partners, and Gainesborough Investments. OmniGuide's progress to date has captured broad attention in both scientific and popular venues.