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Fluoptics gets FDA clearance for its clinical imaging system, Fluobeam®, in the USA

Grenoble – Fluoptics, specializing in fluorescence imaging for guided surgery (FIGS), has obtained the Food and Drug Administration clearance for its clinical imaging system, Fluobeam®. The 510(k) authorization specifies that Fluobeam® can be used clinically with the fluorescent molecule indocyanine green (ICG).

"This FDA clearance opens the door for fluorescence imaging for guided surgery with Fluobeam® in the United States. One year after our clinical imaging system got CE-marked, and was introduced in Europe, Fluobeam® is now available in North American operating rooms, with benefits from this technology coming in a large range of surgical applications. It is a key step for the international development and expansion of the company," rejoiced Odile Allard, chairwoman and CEO of the company.

Fluoptics, which already gets 50% of its revenue from the United States with the sales of its instruments for preclinical research, has just announced the inception of its USA subsidiary with an office in Boston, Massachusetts. This will help to speed up the introduction of its clinical solutions to American private and public hospitals. The United States remains the largest market for medical devices in the world.

« We have great ambitions for the growth of our revenue in the USA market as well as in other foreign countries. The unique performances of Fluobeam® make it clearly ahead of the competition for its image quality and its sensitivity » emphasizes Odile Allard. "We are now considering the different ways to penetrate the market with this new technology, in order to make it available to the largest number of patients as fast as possible ».

The innovative solutions developed by Fluoptics combine an optical imaging system in the near infrared spectrum and injectable fluorescent agents. They assist the surgeon in the operating room during surgery by revealing what cannot be seen with the naked eye. Such solutions have numerous applications in the field of surgical oncology (tumor resection, detection of sentinel lymph nodes) as well as for cardiovascular surgery (monitoring of blood flow), reconstructive surgery (free flap perfusion monitoring) and liver surgery (resection of tumors and metastases).

About Fluoptics

Founded in 2009, Fluoptics develops and markets innovative solutions in the field of fluorescence image-guided surgery. This technology has many applications, among others in surgical oncology, for the resection of tumors and metastasis, for sentinel lymph nodes detection, but also in cardiovascular surgery, reconstructive surgery and liver surgery. Based in Grenoble, Fluoptics has today 13 employees. For more information: www.fluoptics.com

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