



MAUNA KEA TECHNOLOGIES RECEIVES U.S. FDA CLEARANCE FOR ITS NEAR-INFRARED SURGICAL MINIPROBES

FDA 510(k) clearance covers Confocal Miniprobes used with the near-infrared Cellvizio platform for urological and surgical applications

Paris, May 25, 2016 – **Mauna Kea Technologies** (Euronext: MKEA, OTCQX: MKEAY) inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy (CLE) platform, today announced another important regulatory milestone in the US with the 12th 510(k) clearance from United States Food and Drug Administration (FDA). This new FDA clearance covers Confocal Miniprobes indicated for use in urological and minimally invasive surgical applications with the near-infrared Cellvizio platform.

Sacha Loiseau, Ph.D., Co-Founder and CEO of Mauna Kea Technologies, declared, “This FDA clearance is another step forward in expanding the utility of the Cellvizio platform in minimally invasive surgery and urological applications. Our near-infrared imaging products are designed to provide a positive impact on procedural outcomes by adding to fluorescence-guided procedures the precision and reliability of real-time cellular characterization. In addition to be complementary to existing intra-operative fluorescence systems that use the same near-infrared wavelength, surgical CLE data may bring physicians microscopic guidance in a wide range of surgical procedures.”

Image-guided surgery with intra-operative macroscopic fluorescence systems provides surgeons with enhanced anatomical guidance. The addition of microscopic fluorescence tissue pathological assessment may provide immediate, actionable information that may be used to improve diagnostic potential and further guide surgical treatments. The Cellvizio platform with near-infrared miniprobes will be compatible and complementary to existing macroscopic near-infrared endoscopic platforms proposed by a majority of surgical endoscopy manufacturers.

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer thanks to real time in vivo microscopic visualization. The Company’s flagship product, Cellvizio, has received clearance to sell a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, Canada, Brazil and Mexico. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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