

Mauna Kea Technologies Receives FDA Clearance and CE Marking For Its Next-Generation Cellvizio® Platform

The new Cellvizio® platform includes significant improvements and will enable major innovations

Paris and Boston, March 3, 2020 – 6.00 PM CET – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe- and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, announced today that it has obtained 510(k) clearance ([K193416](#)) from the U.S. Food and Drug Administration (FDA) and CE marking of the next-generation Cellvizio® endomicroscopy platform, built with the company's new proprietary system architecture. This marks the 18th U.S. FDA 510(k) clearance of the Cellvizio® pCLE/nCLE platform.

The new Cellvizio incorporates breakthrough modular design solutions to facilitate and better integrate endomicroscopy within procedure suites as well as within third-party platforms. The new platform's hardware and software design was built from the ground up to facilitate future developments, including integration of deep learning (artificial intelligence) capabilities for assisted image interpretation. The ergonomic and significantly reduced footprint, integrates easily with laparoscopic, advanced navigation, and robotic systems. This novel platform is also capable of hosting other proprietary endomicroscopic architectures with imaging capabilities at other wavelengths supporting fluorescence-guided surgery and molecular imaging.

With a completely redesigned user interface, Cellvizio delivers smart workflows for greater efficiency and usability. The all-new touchscreen and single-handed probe connection provide for easier setup and use. Developed to bring precision imaging to more patients with 9 dedicated Confocal Miniprobes™, the new Cellvizio delivers premium imaging capabilities, offering clinicians an efficient high-performing, imaging solution for endoscopy, interventional, and surgical operating suites.

"We are proud to announce the FDA clearance and CE marking of our next generation Cellvizio in the USA and in Europe," said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. "The next generation Cellvizio platform will be launched commercially in the coming months and, with its modular and flexible design as well as being AI and molecular imaging ready, will host our future innovations, indications and support partnership developments."

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 and other diseases thanks to real time *in vivo* microscopic visualization. The Company's flagship product, Cellvizio®, has received clearance/approval in a wide range of applications in more than 40 countries, including the United States, Europe, Japan, and China. For more information on Mauna Kea Technologies, visit www.maunakeatech.com



United States

Mike Piccinino, CFA
Westwicke, an ICR Company
443-213-0500

France and Europe

NewCap - Investor Relations
Alexia Faure
+33 (0)1 44 71 94 94
maunakea@newcap.eu

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