Expanded FDA approval for Cellvizio, 1/18

January 2018—Mauna Kea Technologies has received expanded FDA 510(k) clearance for the Cellvizio 100 series confocal laser microscope and its Confocal Miniprobes. The expanded clearance adds indications for identification of cells and vessels and their organization or architecture. The previously cleared intended use included the fields of gastroenterology, urology, and pulmonology during endoscopic, laparoscopic manual and robot-assisted surgical, and image-guided percutaneous procedures.

The company said the new clearance represents a pivotal milestone for in vivo real-time microscopic visualization technology.

Mauna Kea Technologies, 617-657-1550