

<b>Device Classification Name</b>	<u>Confocal Optical Imaging</u>
<b>510(k) Number</b>	K150831
<b>Device Name</b>	Cellvizio 100 Series System With Confocal Miniprobes
<b>Applicant</b>	MAUNA KEA TECHNOLOGIES 9, Rue D'enghien Paris, FR F-75010
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<b>Regulation Number</b>	<u>876.1500</u>
<b>Classification Product Code</b>	<u>OWN</u>
<b>Date Received</b>	03/30/2015
<b>Decision Date</b>	12/22/2015
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	Gastroenterology/Urology
<b>510k Review Panel</b>	General & Plastic Surgery
<b>Summary</b>	<u>Summary</u>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No