

Device Classification Name	<u>Confocal Optical Imaging</u>
510(k) Number	K151593
Device Name	Cellvizio 100 Series System With Confocal Miniprobes
Applicant	MAUNA KEA TECHNOLOGIES 9 Rue D'enghien Paris, FR 75010
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Regulation Number	<u>876.1500</u>
Classification Product Code	<u>OWN</u>
Date Received	06/12/2015
Decision Date	10/23/2015
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Gastroenterology/Urology
510k Review Panel	General & Plastic Surgery
Summary	<u>Summary</u>
Type	Traditional
Reviewed By Third Party	No
Combination Product	No