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510(k) Premarket Notification



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Device Classification Name	Confocal Optical Imaging ²²
510(k) Number	K183640
Device Name	Cellvizio 100 Series Confocal Laser Imaging Systems And Their Confocal Miniprobes
Applicant	Mauna Kea Technologies 9 Rue D'Enghien Paris, FR 75010
Applicant Contact	Veronique Dentan
Correspondent	Daniel & Daniel Consulting 340 Jones Lane Gardnerville, NV 89460
Correspondent Contact	Michael A. Daniel
Regulation Number	876.1500 ²³
Classification Product Code	OWN ²⁴
Subsequent Product Code	GCJ ²⁵
Date Received	12/26/2018
Decision Date	02/22/2019
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Gastroenterology/Urology
510k Review Panel	General & Plastic Surgery
Summary	Summary ²⁶
Type	Special
Reviewed By Third Party	No
Combination Product	No

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Page Last Updated: 02/17/2020

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