510(k) Premarket Notification

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Device Classification Name	Confocal Optical Imaging[22]
510(k) Number	K191144
Device Name	Cellvizio 100 Series System With 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 Codes	GCJ[25] GWG[26]
Date Received	04/30/2019
Decision Date	01/24/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Gastroenterology/Urology
510k Review Panel	General & Plastic Surgery
Summary	Summary[27]
Type	Traditional
Reviewed By Third Party	No
Combination Product	Yes[28]

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