510(k) Premarket Notification

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Device Classification Name	Endoscope, Neurological[22]
510(k) Number	K180270
Device Name	Cellvizio 100 Series Systems 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	882.1480[23]
Classification Product Code	GWG[24]
Subsequent Product Code	OWN[25]
Date Received	01/31/2018
Decision Date	05/22/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Neurology
510k Review Panel	Neurology
Summary	Summary[26]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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